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TRANSPLANT
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INTERNATIONAL FIGURES ON ORGAN DONATION AND TRANSPLANTATION - 2003

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

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INTERNATIONAL FIGURES ON ORGAN, TISSUE & HEMATOPOIETIC STEM CELL DONATION & TRANSPLANTATION ACTIVITIES. DOCUMENTS PRODUCED BY THE COMMITTEE OF EXPERTS ON THE ORGANISATIONAL ASPECTS OF CO-OPERATION IN ORGAN TRANSPLANTATION (2003).

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Foot Note:
For the purposes of this Newsletter the following definitions were used:
Organ donor: Every potential donor transferred to the operating theatre from whom, at least, one solid organ has been retrieved
Multiorgan donor: Every donor from whom, at least, two different solid organs have been retrieved.
Absolute number: Include all figures corresponding to all donors/patients adults and children
Paediatric: Includes only paediatric activity (patients under 15 years old)

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NEWSLETTER TRANSPLANT 2004

INTRODUCTION

AN INTERNATIONAL FRAMEWORK FOR TRANSPLANTS

Rafael Matesanz
President Transplant Committee Council of Europe

The Council of Europe, set up in 1949, is the oldest European intergovernmental organisation which currently has 44 member states. It is based in Strasbourg and represents approximately 800 million people with the general objective to improve the quality of life for European citizens and defend their human rights. Its decision making body, the Committee of Ministers is composed of the Ministers of Foreign Affairs of the member states. As far as the health field is concerned, the activities are guided by the European Health Committee (CDSP), a steering committee of government representatives. The Council of Europe is the only international organisation dealing with the whole range of health related ethical issues. An example of its activity has been the promotion of the non commercialization of blood, blood products, organs and tissues.

Priority for the CDSP is given to ethics-oriented health policies (equal access, patients' rights, citizens' participation, vulnerable groups such as prisoners, chronically ill and older patients, safety and quality of blood organs and tissues for transplantation and specific selected health policy issues. The CDSP's recommendations provide governments with policy guidelines in a given area. These recommendations are based on advice given by specialized expert committees, either ad hoc, working for a specific period -usually for two years- or permanent ones like the Committee of Experts on the Organisational Aspects of Cooperation in Organ Transplantation (SP-CTO).

The Committee of Experts on the Organisational Aspects of Cooperation in Organ Transplantation was set up following the 3rd Conference of European Health Ministers in Paris in 1987 on the ethical, organisational and legislative aspects on organ transplantation. The Conference considered that the organisational aspects of organ transplantation were particularly important in meeting the organ shortage and that European cooperation was needed to ensure an efficient organisation

The situation in Europe with respect to cadaveric organ donation is very heterogeneous, from very low levels in Eastern countries, under 5 donors per million population (pmp) in most of them, to over 30 donors pmp in Spain, and some regions of Italy, France and Austria. Even in the European Union, cadaveric organ donation can range from 6.4 donors pmp in Greece to 33.8 in Spain (i.e.: 1:5 quotient). The reasons are multiple although it is clear that cannot be attributed to differences in the public predisposition to donate organs but rather to differences in health structure, hospital facilities and especially in the organization of the organ donation system, as analyzed below. The only common point to all the European countries is the ever increasing gap between the number of available organs and the waiting list: wherever more solid organs are obtained, more and more patients are accepted as candidates to be transplanted. As a consequence of this gap, more than 3000 European patients die every year while waiting for organ transplantation. This number however is no doubt underestimated for the lack of expectative to include in the waiting list all the patients clinically suitable. Besides, many countries do not have these data, especially in non vital transplants like the renal or the pancreas. The number of living donors for kidney and liver is however steadily increasing during the last years as an alternative to the shortage of cadaveric organ donors.

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THE ROLE OF OTHER EUROPEAN / INTERNATIONAL BODIES IN THE FIELD OF TRANSPLANTATION: E.U. & WHO

Relevant recommendations of the Council of Europe, important though they are, are not binding with the exception of the Convention. Article 152 of the E.U. Treaty has provided the European Union the opportunity to implement these measures in this field. Transplantation medicine is an important issue for the EU because it is related to the free flow of persons (patients), the free movement of goods (organs and tissues) and of services (implantation medicine is a medical service). The most obvious and least contested area of concern to the EU is the promotion and control of quality and safety of goods and services. Standardised accreditation norms for laboratories and transplantation centres, good laboratory practices (GLPs), good manufacturing practices (GMPs), and the like are essential tools with a view to maintaining high quality standards in this area. In its undertaking, it is clear that the EU should draw upon the experience of the Council of Europe. Whenever appropriate, activities should be undertaken in co-partnership between these two organizations.

Recently EU has finally approved, after three years of elaboration and discussions, the Directive of the European Parliament on “Setting high standards of quality and safety the procurement, testing, processing, storage, and distribution of human tissues and cells in order to ensure a high level of human health protection in the community”. The very important job previously done by the Council of Europe, and the same can be expected in future when organs will be finally approached by the European Union. A permanent observer of EU assists regularly to the SP-CTO meetings and delegates of the Council of Europe participate in most of the activities of the European Union, thus assuring the coordination between these two institutions.

In 1991, the Health Assembly of the WORLD HEALTH ORGANIZATION endorsed a set of Guiding Principles on Human Organ Transplantation. These Guiding Principles -whose emphases include voluntary donation, non-commercialization, genetic relation of recipients to donors and a preference for cadavers over living donors as sources- have considerably influenced professional codes, national, state and provincial legislation, and the policies of intergovernmental organizations. Recently, the WHO Health Assembly has decided that, without any change in their ethical premises, the Guiding Principles and their commentaries may benefit from re-examination in the light of medical and legal developments during the past decade, and from various ethical and practical perspectives identified in the regions. Protection of the person, whether recipient or donor, should remain a priority and needs reinforcement, and additional matters, such as confidentiality and anonymity of both parties, need to be tackled. The Council of Europe and the WHO share obviously the same principles and objectives and are to better coordinate the efforts of both international organizations.

CONCLUSIONS: AN INTERNATIONAL FRAMEWORK

The relevance of SP-CTO during the last 15 years in the field of transplantation has been enormous. It has been the only official standing European committee which approached the problems of organ, tissue and cell donation and transplantation, many years before that any other official institution would come into this field.

It is clear that neither the problems nor the solutions can be isolated or concentrated in a single country or a limited group of them. Persons, goods and services are moving every day in a more free way, first throughout the EU and in the future probably through more and more countries. For this reason it is particularly important a full agreement in the working lines of the different European bodies. The not-for-profit principle is not only a moral notion. There are serious risks involved when economic considerations enter the field. The not-for-profit idea contributes to protection of the donor against the use of his or her body which could be detrimental to his/her health. The not-for-profit idea also contributes towards protecting the health of the recipient. It is a daily reality that one tends to become lenient on safety requirements when trade is involved. Besides, there are too many, often conflicting interests involved with transplantation which are used in health care, to be left entirely to voluntary commitment. So a comprehensive and harmonized regulation is required in this field.

Working lines and areas for cooperation should move around these principles: protection of human rights, protection of health, banning of commercialization (in all its forms), providing for accountability and transparency of the system, non-discrimination criteria in waiting list inclusion or waiting list management and promotion of "learning from each other" in stimulating exchange of experience on various aspects involved, especially in the training of medical staff and organization. The future rules in the Europe of transplantation should include the possibility of tracing donor and recipient at any time. Material coming from so-called third countries should also be subjected to the highest quality and safety standards.

For the Council of Europe, however, and besides these classical priorities of fighting against organ and tissue shortage and promoting an improvement of quality and safety in the field of transplantation, the most important challenge for the coming years will be the transmission of adequate donation and transplantation structures and systems to the emerging countries of the “old” Eastern Europe (we should be sure that in the future there will be no more than one Europe). The recommendations of the Council of Europe, such as those of “Organ Trafficking”, “Donor Registries”, “Waiting Lists Management” and other can be very useful for giving a direction to those countries which start a national program of transplantation. The organization of training courses in transplantation, in the Baltic States or Ukraine, financed by the Council of Europe is also an effective way to implement this cooperation. No doubt we will keep on this pathway in the next future.

It is a responsibility of those countries which during the last decades have reached a good quantitative and qualitative level of activity, in organ and tissue transplantation, to help and give an adequate support to the new states which are now incorporating these therapies to their citizens.

Rafael Matesanz
President Transplant Committee Council of Europe

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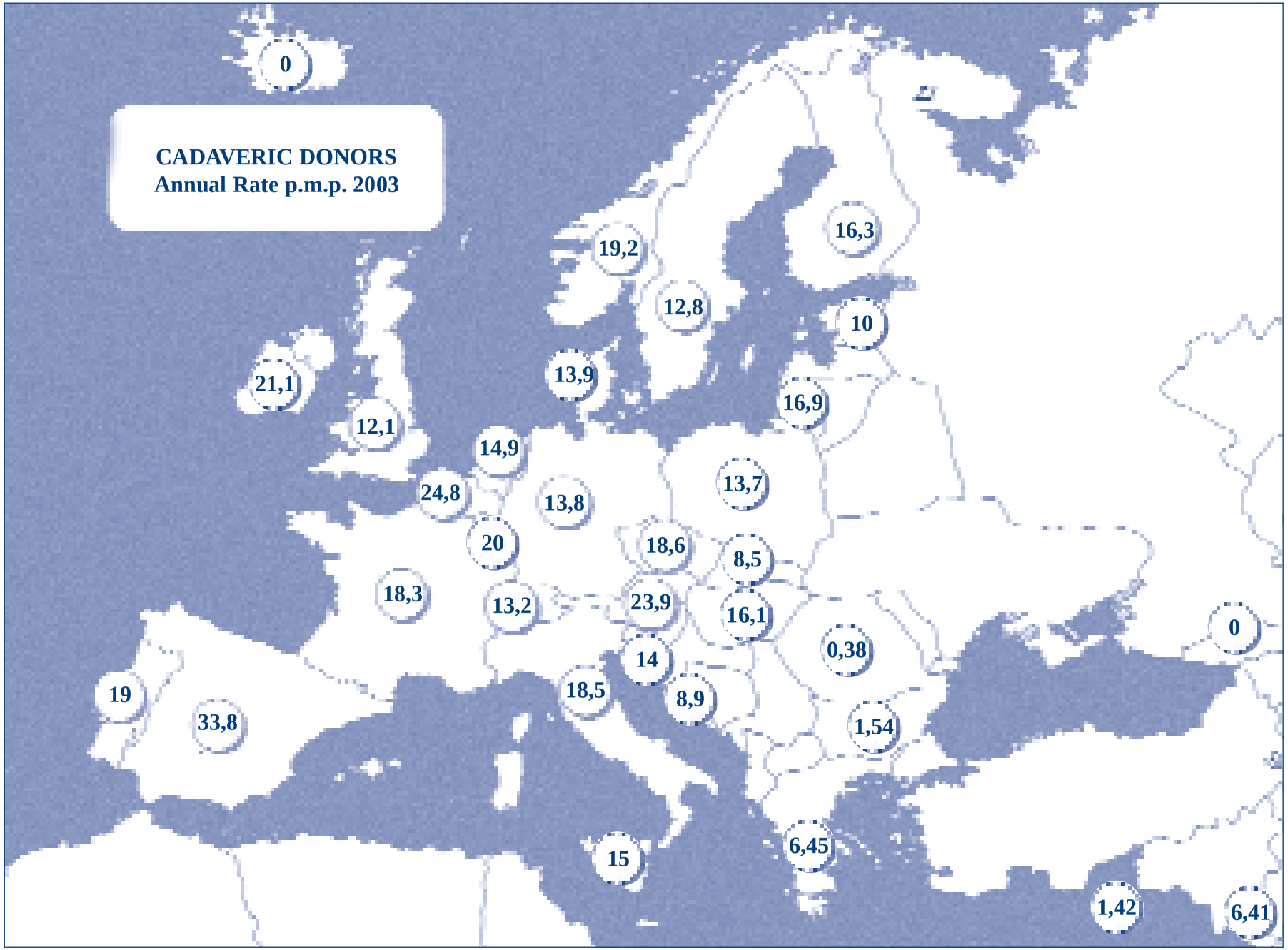
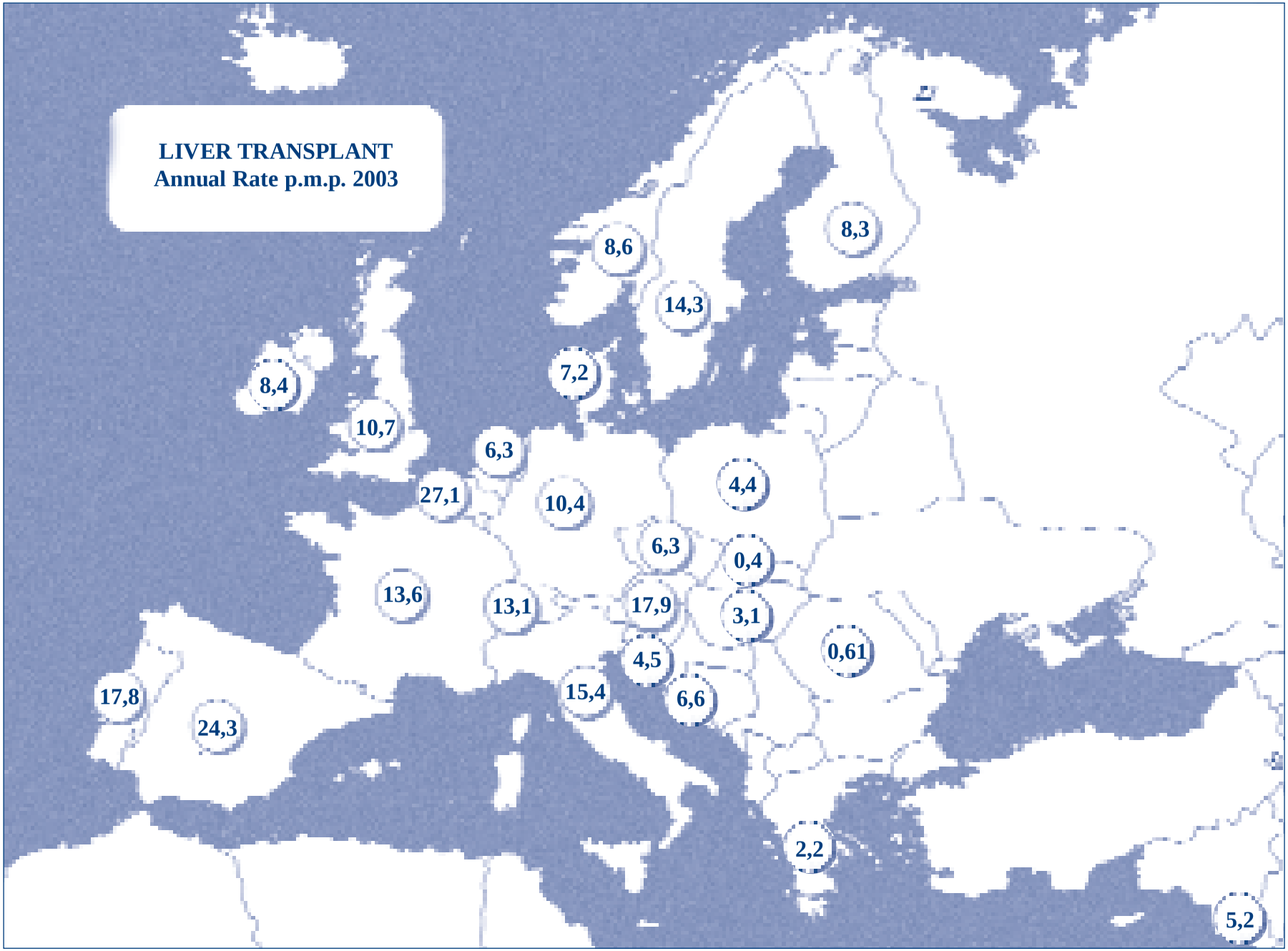
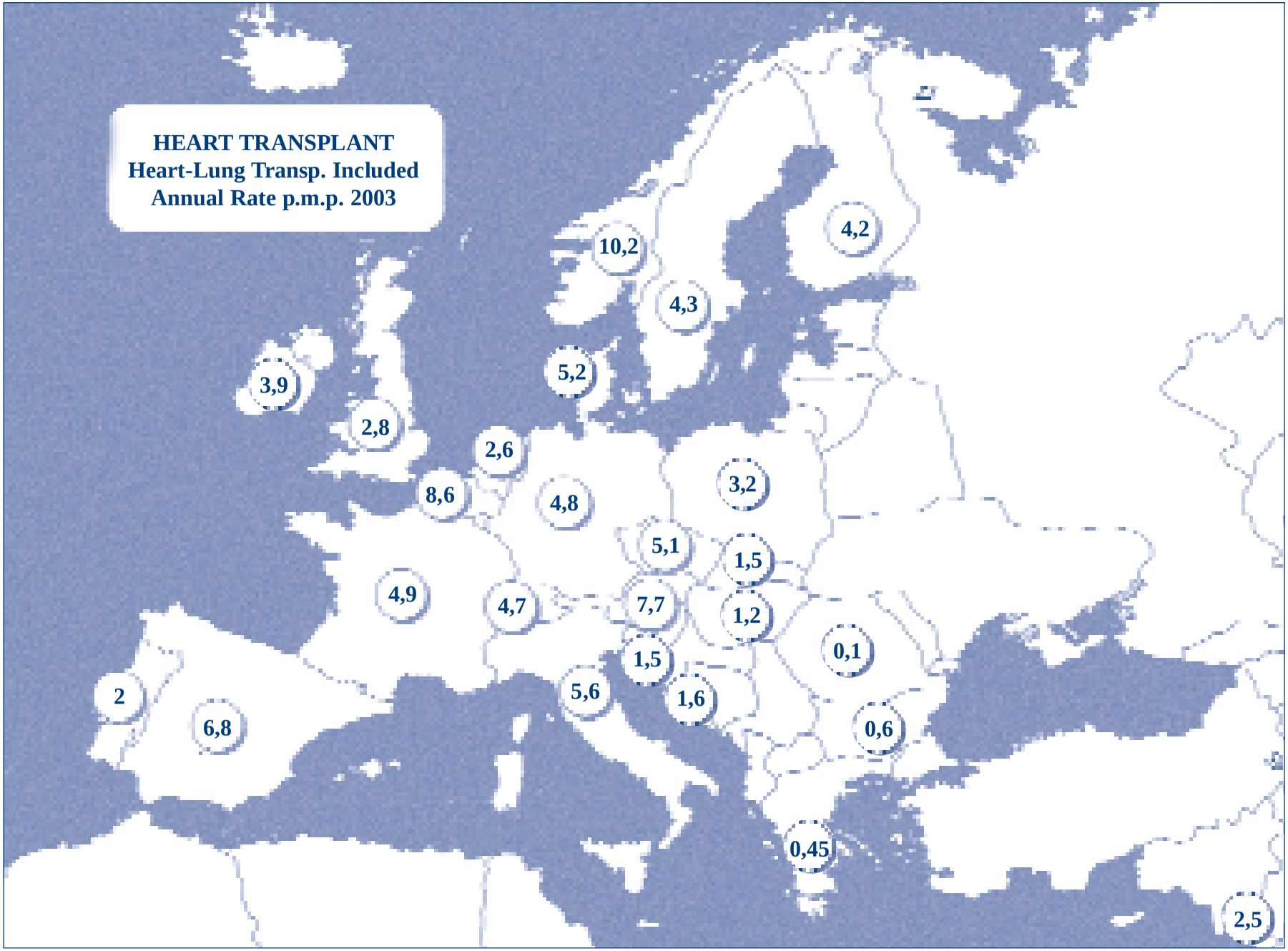
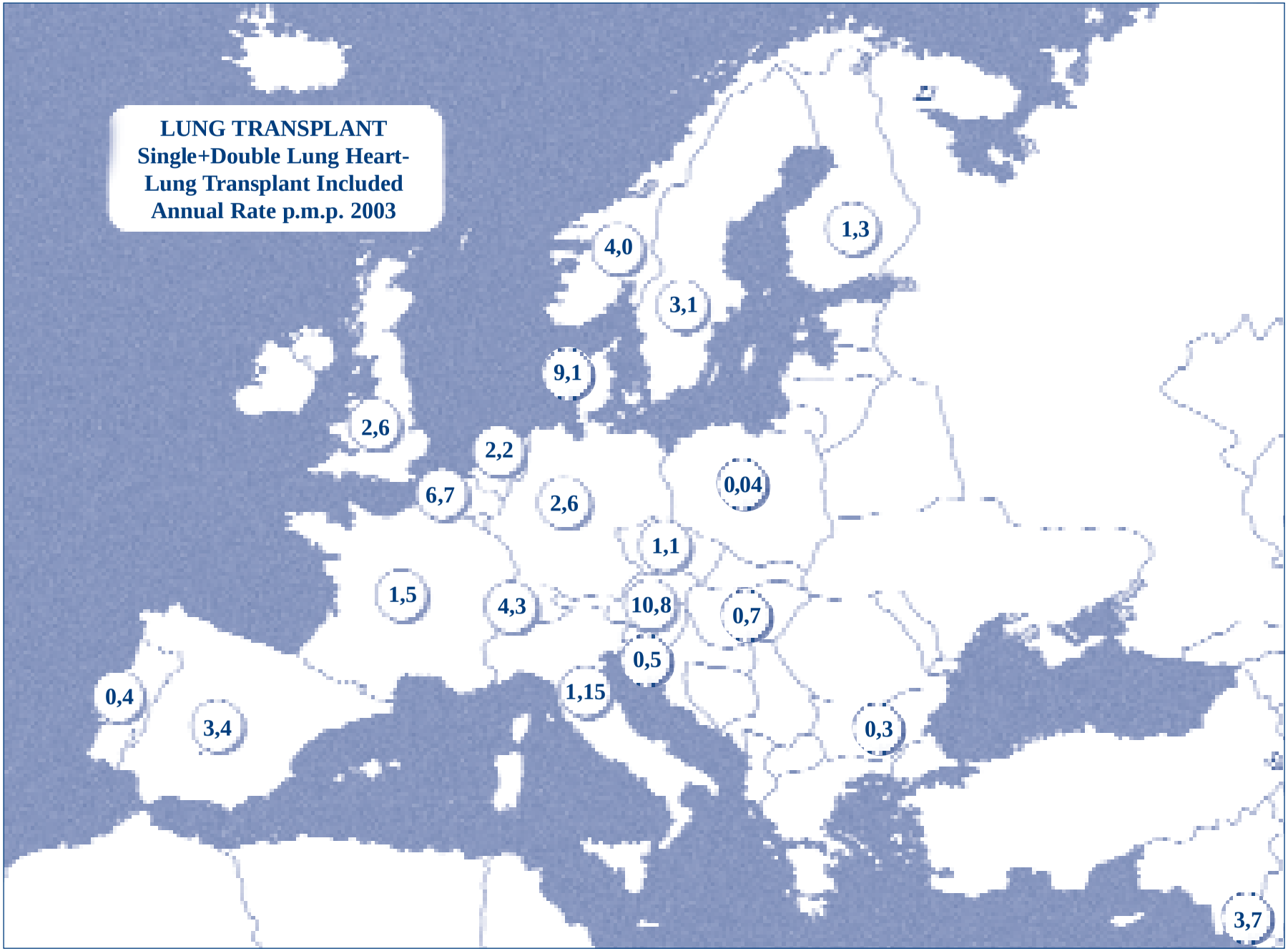
International Figures on organ donation and transplantation year 2003

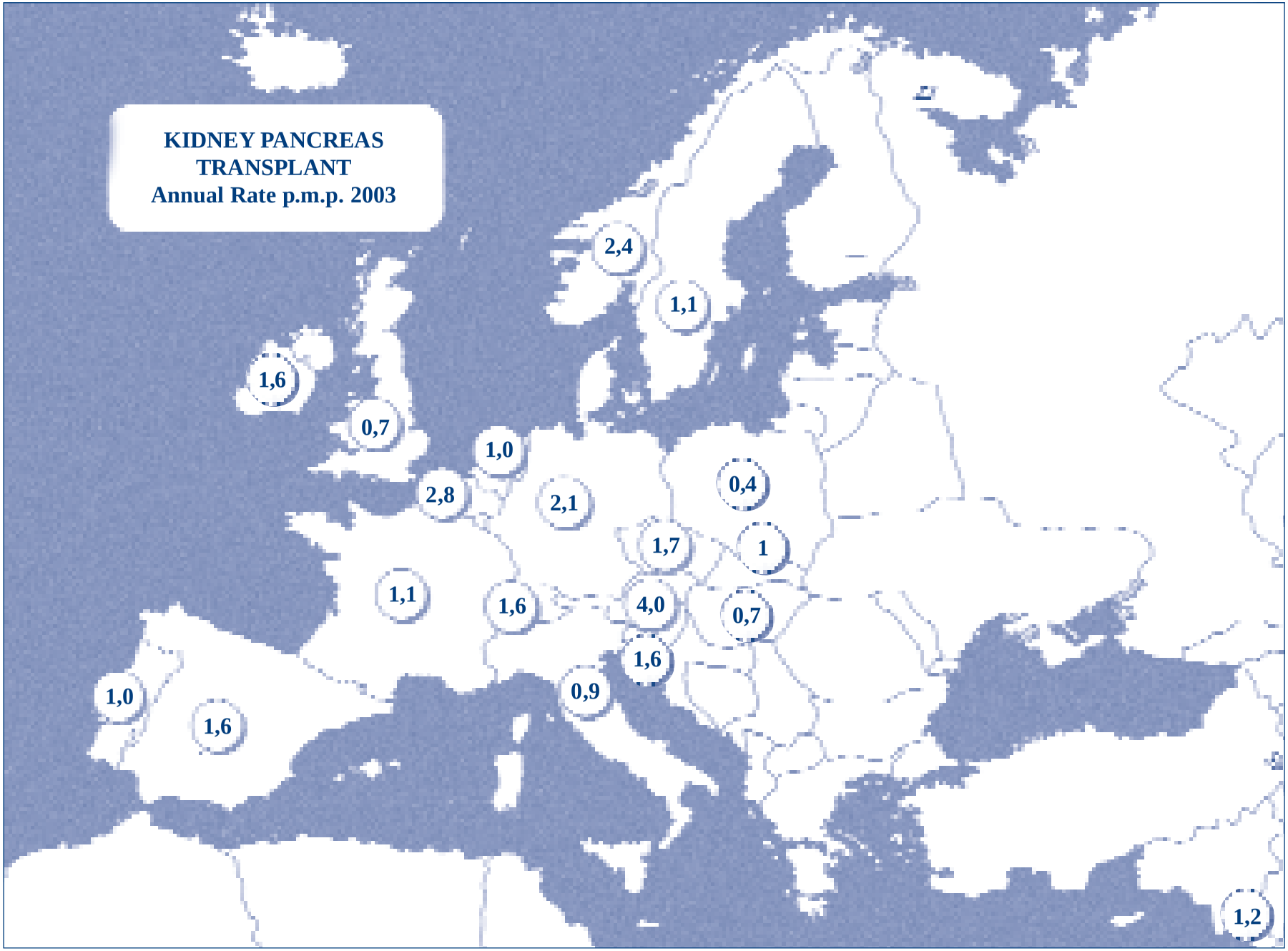

CADAVERIC DONORS
Annual Rate p.m.p. 2003
0
19,2
16,3
12,8
10
21,1
13,9
16,9
12,1
14,9
13,7
24,8
13,8
20
18,6
8,5
18,3
13,2
23,9
16,1
0
0,38
14
19
18,5
8,9
33,8
1,54
15
6,45
1,42
6,41

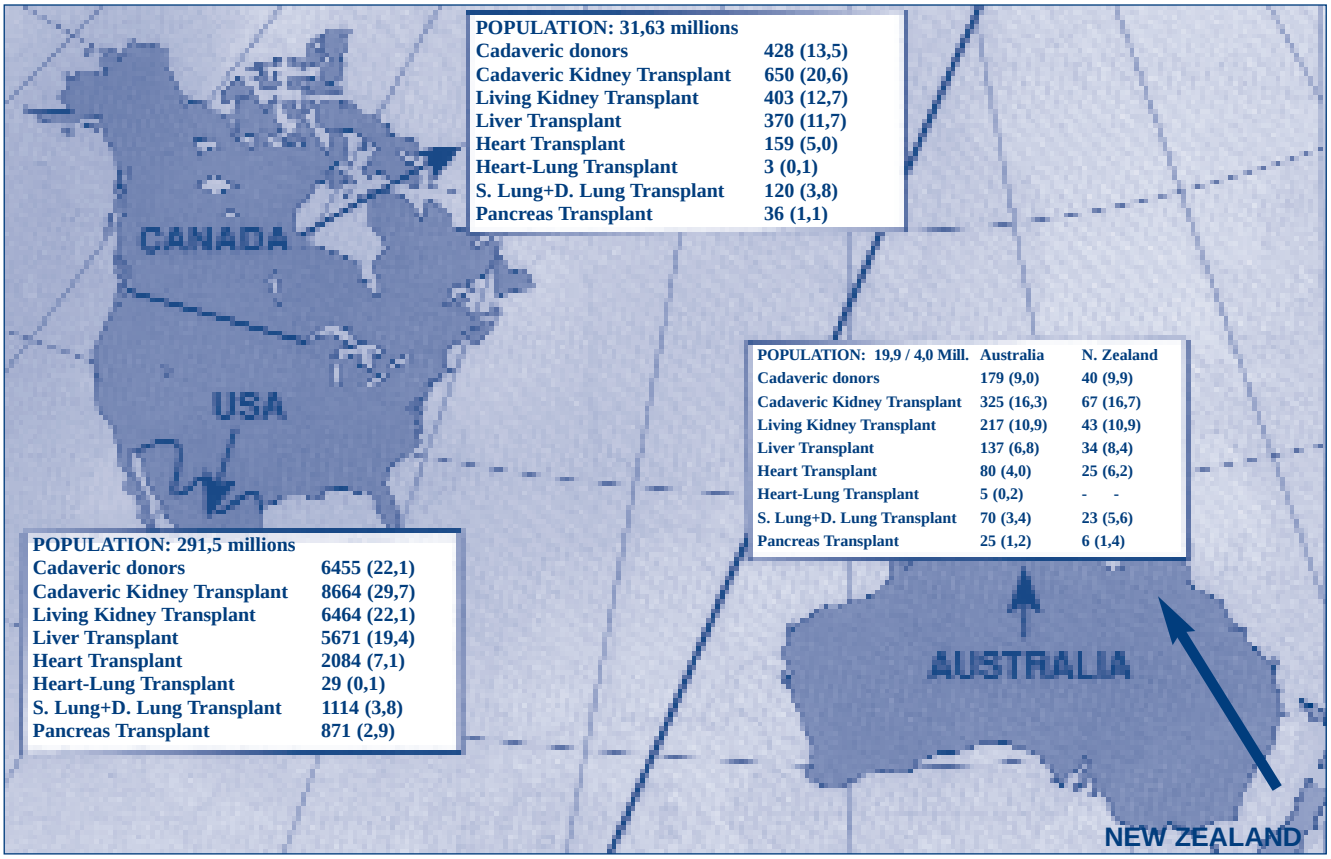

Cadaveric Kidney Transplant
& / Living Kidney Transplant
Annual Rate p.m.p. 2003
0
3,5
34
19,2
30
1,3
24,2
14,6
21,4
0
23,9
8,7
33,4
0
29,1
0
21,1
6,3
25,38
12,2
25,73
1,15
42,14
1,0
25,7
4,9
22,5
0
34,2
4,7
14,8
4,7
32,5
2,2
23,2
14,4
41,71
4,5
29,9
0,5
0
1,4
0,76
7,14
21,5
0
30,5
4,2
26,4
2,4
16,67
0,91
46,7
1,4
21,18
2,05
17,5
2,5
12,2
7,2
2,85
58,6
8,2
10,6


LIVER TRANSPLANT
Annual Rate p.m.p. 2003
8,6
8,3
14,3
7,2
8,4
10,7
6,3
27,1
10,4
4,4
6,3
0,4
13,6
13,1
17,9
3,1
0,61
4,5
15,4
6,6
17,8
24,3
2,2
5,2


HEART TRANSPLANT
Heart-Lung Transp. Included
Annual Rate p.m.p. 2003
10,2
4,2
4,3
5,2
3,9
2,8
2,6
3,2
8,6
4,8
5,1
1,5
4,9
4,7
7,7
1,2
0,1
1,5
5,6
1,6
2
6,8
0,6
0,45
2,5


LUNG TRANSPLANT
Single+Double Lung Heart-
Lung Transplant Included
Annual Rate p.m.p. 2003
4,0
1,3
3,1
9,1
2,6
2,2
6,7
2,6
0,04
1,1
1,5
4,3
10,8
0,7
0,5
1,15
0,4
3,4
0,3
3,7

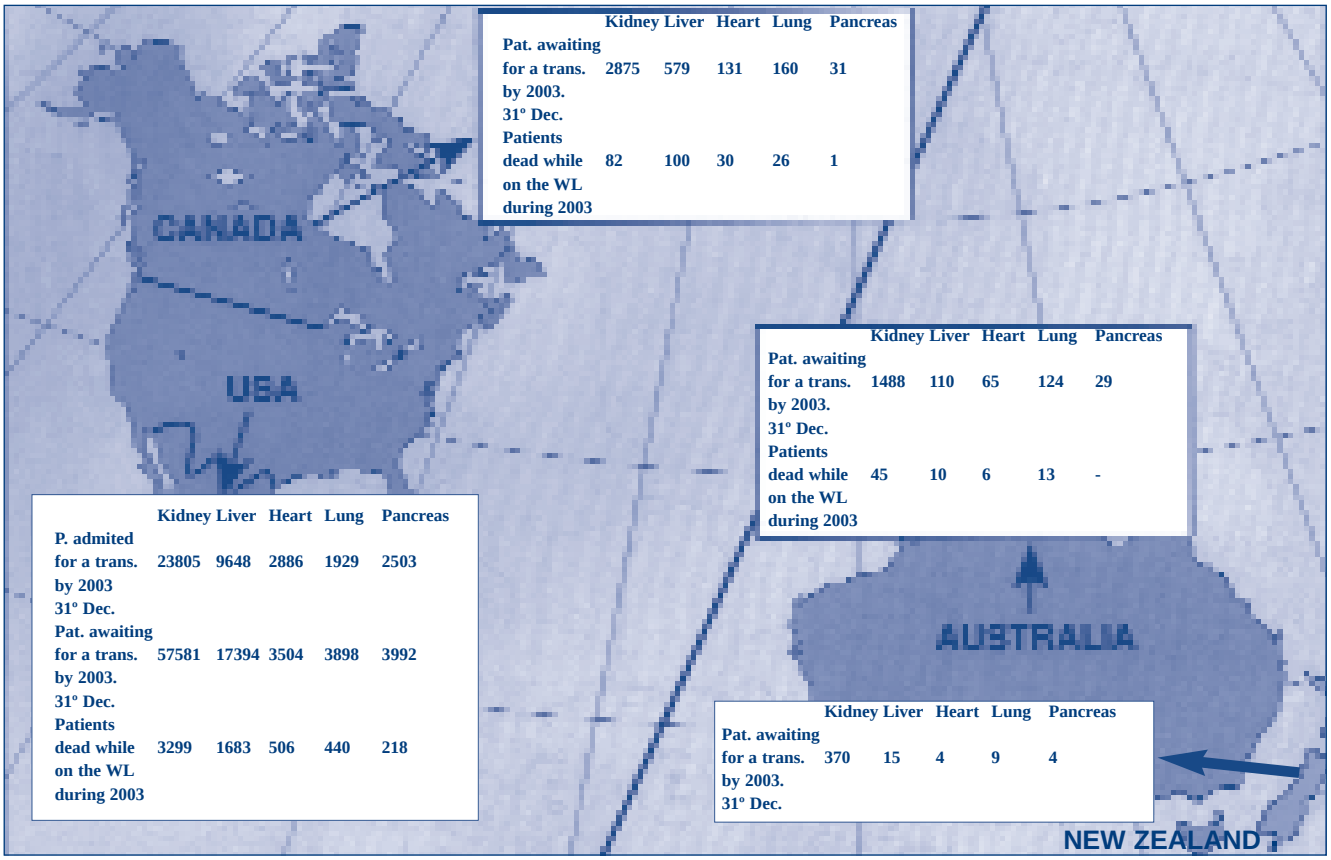

KIDNEY PANCREAS
TRANSPLANT
Annual Rate p.m.p. 2003
2,4
1,1
1,6
0,7
1,0
2,8
2,1
0,4
1,7
1
1,1
1,6
4,0
0,7
1,6
0,9
1,0
1,6
1,2



POPULATION: 31,63 millions	
Cadaveric donors	428 (13,5)
Cadaveric Kidney Transplant	650 (20,6)
Living Kidney Transplant	403 (12,7)
Liver Transplant	370 (11,7)
Heart Transplant	159 (5,0)
Heart-Lung Transplant	3 (0,1)
S. Lung+D. Lung Transplant	120 (3,8)
Pancreas Transplant	36 (1,1)

POPULATION: 19,9 / 4,0 Mill.	Australia	N. Zealand
Cadaveric donors	179 (9,0)	40 (9,9)
Cadaveric Kidney Transplant	325 (16,3)	67 (16,7)
Living Kidney Transplant	217 (10,9)	43 (10,9)
Liver Transplant	137 (6,8)	34 (8,4)
Heart Transplant	80 (4,0)	25 (6,2)
Heart-Lung Transplant	5 (0,2)	- -
S. Lung+D. Lung Transplant	70 (3,4)	23 (5,6)
Pancreas Transplant	25 (1,2)	6 (1,4)

POPULATION: 291,5 millions	
Cadaveric donors	6455 (22,1)
Cadaveric Kidney Transplant	8664 (29,7)
Living Kidney Transplant	6464 (22,1)
Liver Transplant	5671 (19,4)
Heart Transplant	2084 (7,1)
Heart-Lung Transplant	29 (0,1)
S. Lung+D. Lung Transplant	1114 (3,8)
Pancreas Transplant	871 (2,9)



	Kidney	Liver	Heart	Lung	Pancreas
Pat. awaiting for a trans. by 2003. 31° Dec.	2875	579	131	160	31
Patients dead while on the WL during 2003	82	100	30	26	1

	Kidney	Liver	Heart	Lung	Pancreas
Pat. awaiting for a trans. by 2003. 31° Dec.	1488	110	65	124	29
Patients dead while on the WL during 2003	45	10	6	13	-

	Kidney	Liver	Heart	Lung	Pancreas
P. admited for a trans. by 2003 31° Dec.	23805	9648	2886	1929	2503
Pat. awaiting for a trans. by 2003. 31° Dec.	57581	17394	3504	3898	3992
Patients dead while on the WL during 2003	3299	1683	506	440	218

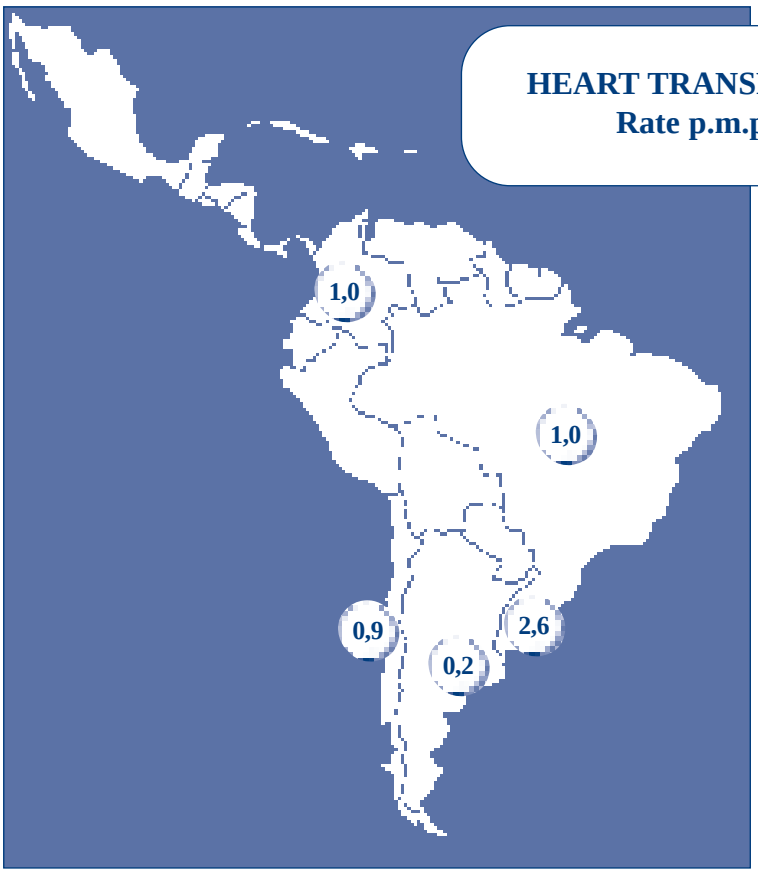
	Kidney	Liver	Heart	Lung	Pancreas
Pat. awaiting for a trans. by 2003. 31° Dec.	370	15	4	9	4

LATIN-AMERICA DONATION&TRANSPLANTATION ACTIVITY DATA

COUNTRIES	ARG	ATG	CHL	CLM	CTR	CUB	SLV	GTM	PNM	PRU	DOM	URG	VEN
Population (million inhab.)	36.5	172	15.5	43	3.9	11.2	6.4	11.7	3	26.7	8.5	3.1	25.5
DONORS	306	1032	139	215	23	-	2	6	16	73	0	50	49

COUNTRIES	ARG	ATG	CHL	CLM	CTR	CUB	SLV	GTM	PNM	PRU	DOM	URG	VEN
Population (million inhab.)	36.5	172	15.5	43	3.9	11.2	6.4	11.7	3	26.7	8.5	3.1	25.5
KIDNEY (Cadaveric/ Living tx)	453/ 164	1376/ 1789	259/ -	387/ -	42/ 63	194/ -	2/ 20	10/ -	27/ 5	127/ 24	-/ 51	77/ 3	84/ 59

HEART TRANSPLANT
Rate p.m.p.



COUNTRIES	ARG	ATG	CHL
Pop. (mill. imhab.)	36,5	172	15,5
HEART (tx)	6	172	14
COUNTRIES	**CLM**	**CTR**	**CUB**
Pop. (mill. imhab.)	43	3,9	11,2
HEART (tx)	43	-	-
COUNTRIES	**SVL**	**GTM**	**PNM**
Pop. (mill. imhab.)	6,4	11,7	3
HEART (tx)	-	-	-
COUNTRIES	**PRU**	**DOM**	**URG**
Pop. (mill. imhab.)	26,7	8,5	3,1
HEART (tx)	-	-	8
COUNTRIES	**VEN**		
Pop. (mill. imhab.)	25,5		
HEART (tx)	-		

PANCREAS TRANSPLANT
Rate p.m.p.

COUNTRIES	ARG	ATG	CHL
Pop. (mill. imhab.)	36,5	172	15,5
PANCREAS (tx)	9	224	0
COUNTRIES	**CLM**	**CTR**	**CUB**
Pop. (mill. imhab.)	43	3,9	11,2
PANCREAS (tx)	5	-	-
COUNTRIES	**SVL**	**GTM**	**PNM**
Pop. (mill. imhab.)	6,4	11,7	3
PANCREAS (tx)	-	-	-
COUNTRIES	**PRU**	**DOM**	**URG**
Pop. (mill. imhab.)	26,7	8,5	3,1
PANCREAS (tx)	-	-	4
COUNTRIES	**VEN**		
Pop. (mill. imhab.)	25,5		
PANCREAS (tx)	-		

COUNTRIES	ARG	ATG	CHL	CLM	CTR	CUB	SLV	GTM	PNM	PRU	DOM	URG	VEN
Population (million inhab.)	36.5	172	15.5	43	3.9	11.2	6.4	11.7	3	26.7	8.5	3.1	25.5
LIVER (tx)	176	809	62	86	-	-	-	-	-	6	-	0	4

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International data on organ donation, trasplantation, waiting list and family refusals. Year 2003

COUNTRIES	AUSTRIA	BELGIUM	BULGARIA	CZECH R	CROATIA	CYPRUS	DENMARK	ESTONIA	FINLAND	FRANCE	GEORGIA	GERMANY
Population												
(million inhabitants)	8.2	10.3	7.8	10.29	4.38	0.7	5.4	1.40	5.2	61.26	5	82.2
DONATION												
Cadaveric donors	191	251	12	191	39	1	75	14	85	1119	-	1133
Rate (pmp)	23.29	24.37	1.54	18.6	8.9	1.42	13.9	10	16.3	18.3	-	13.78
NHB donors (pmp)	2(0.24)	14(1.36)	-	2(0.2)	-	-	-	-	-	-	-	-
Pediatric <15 years	3	15	-	-	1	-	4	1	2	37	-	53
% Multiorgan donors	80.1	88		56	-	-	57.33	-	55	75	-	74
TRANSPLANTATION												
KIDNEY												
Cadaveric transplants	342	434	17	352	73	2	129	30	156	1991	-	2111
Rate (pmp)	41.71	42.14	2.18	34.2	16.67	2.85	23.9	21.4	30.0	32.5	-	25.68
Paediatric <15 years	8	14	2	8	1	-	5	3	9	50	-	76
Living transplant	37	10	16	48	4	41	47	2.1	7	136	7	404
Rate (pmp)	4.5	1.0	2.05	4.7	0.91	58.6	8.7	-	1.3	2.2	1.4	4.9
Paediatric <15 years	3	3	-	1	-	-	1	-	-	5	1	14
LIVER												
Transplants (Included all combinations)	147	279	-	65	29	-	39	-	43	833	-	855
Rate (pmp)	17.93	27.09	-	6.3	6.62	-	7.2	-	8.3	13.6	-	10.40
Paediatric <15 years	-	-	-	3	4	-	5	-	2	69	-	-
Split liver transplants	7	23	-	-	4	-	-	-	-	71	-	101
Split liver paediatric	5	11	-	-	3	-	-	-	-	26	-	57
Domino liver transp.	-	2	-	-	-	-	-	-	-	14	-	8
Domino liver paed.	-	-	-	-	-	-	-	-	-	0	-	1
Living liver transp.	6	40	-	1	1	-	2	-	-	42	-	74
Living liver paediatric	5	12	-	1	1	-	2	-	-	11	-	24
HEART												
Transplants												
(included Heart-lung transpt)	63	89	5	52	7	-	28	-	22	299	-	394
Rate (pmp)	7.68	8.64	0.64	5.1	1.6	-	5.2	-	4.2	4.9	-	4.79
Paediatric <15 years	5	2	-	1	-	-	2	-	5	11	-	35
HEART-LUNG												
Transplants	1	1	1	-	-	-	1	-	1	16	-	20
Rate (pmp)	0.12	0.10	0.13	-	-	-	0.2	-	0.2	0.3	-	0.24
Paediatric <15 years	-	1	-	-	-	-	-	-	-	2	-	2
LUNG												
Single lung	16	28	1	7	-	-	36	-	1	15	-	46
Rate (pmp)	2	2.7	0.13	0.7	-	-	6.7	-	0.2	0.2	-	0.6
Double lung	72	41	1	4	-	-	13	-	6	77	-	166
Rate (pmp)	8.8	4	0.13	0.4	-	-	2.4	-	1.1	1.3	-	2
S+D Lung (rate) (included Heart-lung transpt)	88(10.8)	69(6.7)	2(0.26)	11(1.1)	-	-	49(9.1)	-	7(1.3)	92(1.5)	-	212(2.6)
NHB S+D Lung (rate)	-	-	-	-	-	-	-	-	-	-	-	-
Paediatric < 15 years	2	1	-	1	-	-	-	-	-	3	-	6
PANCREAS												
Kid-panc tranp(rate)	33(4.02)	29(2.82)	-	17(1.7)	7 (1.6)	-	-	-	-	65(1.1)	-	169(2.06)
Isolate panc. (rate)	-	-	-	6(0.6)	1 (0.23)	-	-	-	-	5(0.1)	-	-
O. combinations (rate)	1(0.12)	1(0.1)	-	-	-	-	-	-	-	-	-	1(0.01)
SMALL BOWEL												
Isolate sb tx. (rate)	-	-	-	-	-	-	-	-	-	0.05	-	6
Isolate sb ped. (rate)	-	-	-	-	-	-	-	-	-	0.05	-	-
O. comb (rate)	-	-	-	-	-	-	-	-	-	0.03	-	-
O comb ped. (rate)	-	-	-	-	-	-	-	-	-	0.02	-	-

COUNTRIES	GREECE	HUNGARY	ICELAND	ITALY	ISRAEL	LATVIA	LUXEMB.	MALTA	NETHERL.	NORWAY	POLAND	PORTUGAL
Population												
(million inhabitants)	11	10	289.272	56.3	6.7	2.30	0.4	0.4	16	4.52	38.23	10
DONATION												
Cadaveric donors	71	161	-	1042	43	39	8	6	239	87	525	190
Rate (pmp)	6.45	16.1	-	18.5	6.41	16.9	20	15	14.94	19.2	13.7	19
NHB donors (pmp)	-	-	-	-	-	-	-		98(6.13)	1	-	-
Pediatric <15 years	2	7	-	37	6	-	-		14	10	27	6
% Multiorgan donors	85.9	36	-	72.2	95.5	-	87.5		51.0	-	38	-
TRANSPLANTATION												
KIDNEY												
Cadaveric transplants	134	299	-	1489	55	67	9	7	406	154	984	315
Rate (pmp)	12.2	29.9	-	26.4	8.2	29.1	22.5	17.5	25.38	34	25.73	30.5
Paediatric <15 years	5	14	-	64	9	-	-		12	1	38	13
Living transplant	79	5	1	135	71	-	-	1	195	87	44	42
Rate (pmp)	7.2	0.5	3.5	2.4	10.59	-	-	2.5	12.2	19.2	1.15	4.2
Paediatric <15 years	-	-	-	-	8	-	-		5	7	7	-
LIVER												
Transplants (Included all combinations)	24	31	-	867	35	-	-	-	101	39	168	178
Rate (pmp)	2.2	3.1	-	15.4	5.22	-	-	-	6.31	8.6	4.39	17.8
Paediatric <15 years	-	-	-	31	2	-	-	-	-	5	30	10
Split liver transplants	-	-	-	78	1	-	-	-	6	-	-	2
Split liver paediatric	-	-	-	-	1	-	-	-	4	-	-	-
Domino liver transp.	-	-	-	-	-	-	-	-	1	-	-	38
Domino liver paed.	-	-	-	-	-	-	-	-	-	-	-	-
Living liver transp.	-	-	-	30	9	-	-	-	-	-	12	6
Living liver paediatric	-	-	-	-	3	-	-	-	-	-	11	-
HEART												
Transplants												
(included Heart-lung transpt)	5	12	-	317	17	-	-	-	41	46	122	20
Rate (pmp)	0.45	1.2	-	5.6	2.53	-	-	-	2.56	10.2	3.19	2.0
Paediatric <15 years	-	-	-	10	2	-	-	-	1	3	1	-
HEART-LUNG												
Transplants	-	-	-	-	2	-	-	-	1	1	1	-
Rate (pmp)	-	-	-	-	0.29	-	-	-	0.06	-	0.02	-
Paediatric <15 years	-	-	-	-	1	-	-	-	-	-	-	-
LUNG												
Single lung	-	-	-	34	14	-	-	-	7	3	1	-
Rate (pmp)	-	-	-	0.60	2.08	-	-	-	0.4	0.2	0.02	-
Double lung	-	7	-	31	9	-	-	-	28	17	1	4
Rate (pmp)	-	0.7	-	0.55	1.34	-	-	-	1.8	3.8	0.02	0.4
S+D Lung (rate) (included Heart-lung transpt)	-	7(0.7)	-	65(1.15)	23(3.73)	-	-	-	35(2.2)	20(4)	2(0.04)	4(0.4)
NHB S+D Lung (rate)	-	-	-	-	-	-	-	-	-	-	-	-
Paediatric < 15 years	-	-	-	-	1	-	-	-	-	-	-	-
PANCREAS												
Kid-panc tranp(rate)	-	7(0.7)	-	53(0.94)	8(1.19)	-	-	-	16(1.0)	11(2.4)	14(0.36)	10(1.0)
Isolate panc. (rate)	-	-	-	23(0.41)	1(0.14)	-	-	-	-	2(0.4)	-	-
O. combinations (rate)	-	-	-	1(0.02)	-	-	-	-	-	5(1.12)	-	-
SMALL BOWEL												
Isolate sb tx. (rate)	-	-	-	0.05	-	-	-	-	-	-	-	-
Isolate sb ped. (rate)	-	-	-	-	-	-	-	-	-	-	-	-
O. comb (rate)	-	-	-	0.02	-	-	-	-	-	-	1	-
O comb ped. (rate)	-	-	-	-	-	-	-	-	-	-	-	-

COUNTRIES	IRELAND	ROMANIA	SLOVAK R.	SLOVENIA	SPAIN	SWEDEN	SWITZERL	UK	AUSTRALIA	N. ZEAL.	USA	CANADA
Population (million inhabitants)	3.8	21	5.3	2	42.72	8.9	7.2	59.0	19.881.469	4.009.200	291,500	31.63
DONATION												
Cadaveric donors	80	8	46	28	1443	114	95	711	179	40	6455	428
Rate (pmp)	21.1	0.38	8.5	14	33.8	12.8	13.2	12.1	9	9.9	22.1	13.5
NHB donors (pmp)	-	-	-	-	56(1.31)	-	6(0.8)	66(1.1)	1(0.05)	-		-
Pediatric <15 years	8	-	2	1	68	4	4	32	12	2	886	-
% Multiorgan donors	85	75	-	79	56	90	84	84	82	93	83	-
TRANSPLANTATION												
KIDNEY												
Cadaveric transplants	127	16	80	43	1991	215	167	1246	325	67	8664	650
Rate (pmp)	33.4	0.76	14.8	21.5	46.7	24.2	23.2	21.1	16.3	16.7	29.7	20.6
Paediatric <15 years	5	-	2	1	62	-	6	52	22(5.5)	3	381	-
Living transplant	-	150	24	-	60	130	104	442	217	43	6464	403
Rate (pmp)	-	7.14	4.7	-	1.4	14.6	14.4	7.5	10.9	10.9	22.1	12.7
Paediatric <15 years	-	2	3	-	5	11	9	33	-	-	430	-
LIVER												
Transplants (Included all combinations)	32	13	2	9	1037	127	93	633	137	34	5671	370
Rate (pmp)	8.4	0.61	0.4	4.5	24.34	14.3	13.1	10.7	6.8	8.4	19.4	11.7
Paediatric <15 years	-	4	1	-	54	5	9	76	10	1	546	-
Split liver transplants	-	1	1	-	16	5	2	79	17	7	-	-
Split liver paediatric	-	1	0.2	-	6	-	2	-	-	-	-	-
Domino liver transp.	-	-	-	-	11	7	1	3	-	-	-	-
Domino liver paed.	-	-	-	-	-	-	-	-	-	-	-	-
Living liver transp.	-	6	-	-	31	5	-	3	1	-	320	35
Living liver paediatric	-	3	-	-	5	2	-	2	0.05	-	68	-
HEART												
Transplants	15	2	8	3	290	38	34	163	80	25	2084	159
Rate (pmp)	3.9	0.1	1.5	1.5	6.8	4.3	4.7	2.8	4	6.2	7.1	5.0
Paediatric <15 years	-	-	-	-	14	4	1	26	3	4	293	-
HEART-LUNG												
Transplants	-	-	-	-	3	2	-	15	5	-	29	3
Rate (pmp)	-	-	-	-	0.07	0.2	-	0.3	0.2	-	0.09	0.1
Paediatric <15 years	-	-	-	-	-	-	-	1	-	-	6	-
LUNG												
Single lung	-	-	-	1	48	14	-	38	11	9	-	21
Rate (pmp)	-	-	-	0.5	1.12	1.6	-	0.6	0.5	2.2	-	0.7
Double lung	-	-	-	-	97	13	31	113	59	14	-	99
Rate (pmp)	-	-	-	-	2.27	1.5	4.3	1.9	2.9	3.4	-	3.1
S+D Lung (rate) (included Heart-lung transpt)	-	-	-	1(0.5)	145(339)	24(3.1)	31(4.3)	151(2.6)	70(3.4)	23(5.6)	1114(3.8)	120(3.8)
NHB S+D Lung (rate)	-	-	-	-	4(0.09)	-	-	-	-	-	-	-
Paediatric < 15 years	-	-	-	-	10	-	2	-	2	-	53	-
PANCREAS												
Kid-panc tranp(rate)	6(1.6)	-	1	-	67(1.57)	10(1.1)	12(1.6)	42(0.7)	25(1.2)	6(1.4)	871(2.98)	36 (1.1)
Isolate panc. (rate)	-	-	0.2	-	3(0.07)	-	2(0.3)	12(0.2)	6(0.3)	-	502(1.7)	27 (0.9)
O. combinations (rate)	-	-	-	-	4(0.09)	-	16(2.5)	-	-	-	-	-
SMALL BOWEL												
Isolate sb tx. (rate)	-	-	-	-	1(0.02)	-	-	0.2	-	-	116(0.39)	0.1
Isolate sb ped. (rate)	-	-	-	-	1(0.02)	-	-	0.2	-	-	73	-
O. comb (rate)	-	-	-	-	6(0.11)	-	-	-	-	-	-	0.1
O comb ped. (rate)	-	-	-	-	4(0.09)	-	-	-	-	-	-	-

COUNTRIES	AUSTRIA	BELGIUM	BULGARIA	CZECH R.	CROATIA	CYPRUS	DENMARK	ESTONIA	FINLAND	FRANCIA	GEORGIA	GERMANY
Population (million inhabitants)	8.2	10.3	7.8	10.29	4.38	0.7	5.4	1.40	5.2	61.26	5	82.2
WAITING LIST												
KIDNEY												
Nº TRANSP. CENTRES:	5	7	2	7	-	1	4	1	1	45	2	41
Patients admitted to the waiting list during 2003	399	454	176	417	165	26	231	28	241	2571	-	2693
Patients awaiting for a transplant by 2003, 31st Dec	967	1065	766	676	812	120	377	47	269	5380	-	12150
Patients dead while on the WL during 2003	58	25	31	41	-	4	10	5	2	113	-	437
LIVER												
Nº TRANSP. CENTRES:	3	6	-	2	-	-	1	1	1	24	-	25
Patients admitted to the waiting list during 2003	207	335	19	87	48	-	51	2	43	1092	-	1429
Patients awaiting for a transplant by 2003, 31st Dec	161	232	17	40	74	-	17	2	6	460	-	1613
Patients dead while on the WL during 2003	36	41	2	3	-	-	1	-	2	100	-	307
HEART												
Nº TRANSP. CENTRES:	3	7	1	2	-	-	2	-	1	27	-	28
Patients admitted to the waiting list during 2003	111	102	14	69	4	-	24	-	30	391	-	761
Patients awaiting for a transplant by 2003, 31st Dec	128	57	8	66	14	-	14	-	7	310	-	697
Patients dead while on the WL during 2003	18	14	6	10	-	-	0	-	4	89	-	149
LUNG												
Nº TRANSP. CENTRES:	2	3	1	1	-	-	2	-	1	12	-	11
Patients admitted to the waiting list during 2003	95	83	-	22	-	-	24	-	11	151	-	353
Patients awaiting for a transplant by 2003, 31st Dec	57	72	-	16	-	-	14	-	5	177	-	518
Patients dead while on the WL during 2003	10	8	-	7	-	-	0	-	-	44	-	85
PANCREAS												
Nº TRANSP. CENTRES:	3	6	-	1	-	-	-	-	-	9	-	27
Patients admitted to the waiting list during 2003	46	58	-	8	15	-	-	-	-	27	-	169
Patients awaiting for a transplant by 2003, 31st Dec	55	75	-	9	6	-	-	2	-	202	-	288
Patients dead while on the WL during 2003	-	1	-	-	-	-	-	-	-	10	-	14
SMALL BOWEL												
Nº TRANSP. CENTRES:	-	-	-	-	-	-	-	-	-	1	-	-
Patients admitted to the waiting list during 2003	-	-	-	-	-	-	-	-	-	8	-	-
Patients awaiting for a transplant by 2003, 31st Dec	-	-	-	-	-	-	-	-	-	9	-	-
Patients dead while on the WL during 2003	-	-	-	-	-	-	-	-	-	-	-	-

COUNTRIES Population (million inhabitants)	GREECE 11	HUNGARY 10	ICELAND 289.272	ITALY 56.3	ISRAEL 6.7	LATVIA 2.30	LUXEMB 0.4	MALTA 0.4	NETHER-LANDS 16	NORWAY 4.52	POLAND 38.23	PORTUGAL 10	IRELAND 3.8
WAITING LIST													
KIDNEY													
Nº TRANSP. CENTRES:	4	4	1	39	6	1	1	1	7	1	18	8	1
Patients admitted to the waiting list during 2003	176	370	-	2543	179	34	15	15	756	169	1194	-	165
Patients awaiting for a transplant by 2003, 31st Dec	824	999	-	8170	469	337	27	90	2372	187	2435	-	248
Patients dead while on the WL during 2003	15	53	-	113	16	11	-	4	123	16	53	-	1
LIVER													
Nº TRANSP. CENTRES:	1	1	-	19	3	-	-	-	3	1	7	3	1
Patients admitted to the waiting list during 2003	55	96	-	1166	96	-	-	-	148	37	259	-	43
Patients awaiting for a transplant by 2003, 31st Dec	117	42	-	1544	110	-	-	-	153	3	95	-	17
Patients dead while on the WL during 2003	20	13	-	131	14	-	-	-	20	1	29	-	2
HEART													
Nº TRANSP. CENTRES:	1	1	-	17	3	-	-	1	3	1	4	4	1
Patients admitted to the waiting list during 2003	10	32	-	426	43	-	-	2	64	45	224	-	-
Patients awaiting for a transplant by 2003, 31st Dec	7	25	-	648	116	-	-	4	45	4	129	-	-
Patients dead while on the WL during 2003	-	7	-	81	15	-	-	0	12	-	43	-	-
LUNG													
Nº TRANSP. CENTRES:	1	-	-	10	1	-	-	-	2	1	1	1	-
Patients admitted to the waiting list during 2003	1	8	-	139	32	-	-	-	54	27	4	-	-
Patients awaiting for a transplant by 2003, 31st Dec	1	1	-	234	39	-	-	-	79	40	3	-	-
Patients dead while on the WL during 2003	-	-	-	49	7	-	-	-	15	8	-	-	1
PANCREAS													
Nº TRANSP. CENTRES:	-	1	-	15	3	-	-	-	2	1	2	2	5
Patients admitted to the waiting list during 2003	-	15	-	59	11	-	-	-	29	16	52	-	12
Patients awaiting for a transplant by 2003, 31st Dec	-	27	-	192	-	-	-	-	46	10	16	-	-
Patients dead while on the WL during 2003	-	-	-	10	-	-	-	-	5	1	1	-	-
SMALL BOWEL													
Nº TRANSP. CENTRES:	-	-	-	1	-	-	-	-	-	-	-	-	-
Patients admitted to the waiting list during 2003	-	-	-	3	-	-	-	-	-	-	-	-	-
Patients awaiting for a transplant by 2003, 31st Dec	-	-	-	21	-	-	-	-	-	-	-	-	-
Patients dead while on the WL during 2003	-	-	-	-	-	-	-	-	-	-	-	-	-

COUNTRIES	ROMANIA	SLOVENIA	SLOVAK R.	SPAIN	SWEDEN	SWITZER-LAND	U. K.	AUSTRALIA	N. ZEALAND	USA	CANADA
Population (million inhabitants)	21	2	5.3	42.72	8.9	7.2	59.0	19.881.469	4.009.200	291.5	31.63
WAITING LIST											
KIDNEY											
Nº TRANSP. CENTRES:	4	1	-	42	4	6	26	20	3	250	23
Patients admitted to the waiting list during 2003	413	44	217	-	341	310	2379	-	-	23805	-
Patients awaiting for a transplant by 2003, 31st Dec	1396	123	752	4026	402	490	6581	1488	370	57581	2875
Patients dead while on the WL during 2003	82	1	98	NG	5	11	269	45	-	3299	82
LIVER											
Nº TRANSP. CENTRES:	1	1	-	24	3	4	8	8	1	117	8
Patients admitted to the waiting list during 2003	87	11	16	1490	145	124	845	-	-	9648	-
Patients awaiting for a transplant by 2003, 31st Dec	180	9	20	631	31	87	254	110	15	17394	569
Patients dead while on the WL during 2003	21	5	6	172	5	28	70	10	-	1683	100
HEART											
Nº TRANSP. CENTRES:	2	1	-	18	3	5	7	5	1	131	12
Patients admitted to the waiting list during 2003	21	11	16	407	44	51	196	-	-	2886	-
Patients awaiting for a transplant by 2003, 31st Dec	59	10	7	112	14	18	110	65	4	3504	131
Patients dead while on the WL during 2003	5	1	4	31	3	9	10	6	-	506	30
LUNG											
Nº TRANSP. CENTRES:	-	1	-	7	2	3	6	3	1	67	5
Patients admitted to the waiting list during 2003	-	1	-	242	46	32	175	-	-	1929	-
Patients awaiting for a transplant by 2003, 31st Dec	-	-	-	128	26	20	269	124	9	3898	160
Patients dead while on the WL during 2003	-	-	-	34	6	6	33	13	-	440	26
PANCREAS											
Nº TRANSP. CENTRES:	-	-	-	10	4	2	15	2	1	141	7
Patients admitted to the waiting list during 2003	-	-	2	84	12	14	86	-	-	2503	-
Patients awaiting for a transplant by 2003, 31st Dec	-	-	10	75	4	5	152	29	4	3992	31
Patients dead while on the WL during 2003	-	-	-	2	-	1	9	-	-	218	1
SMALL BOWEL											
Nº TRANSP. CENTRES:	-	-	-	2	1	1	2	-	-	18	3
Patients admitted to the waiting list during 2003	-	-	-	6	-	-	3	-	-	195	-
Patients awaiting for a transplant by 2003, 31st Dec	-	-	-	6	3	-	1	-	-	189	0
Patients dead while on the WL during 2003	-	-	-	3	-	-	-	-	-	47	1

FAMILY REFUSALS 2003

COUNTRIES	AUSTRIA	BELGIUM	BULGARIA	CZECH. R.	CROATIA	CYPRUS	DENMARK	ESTONIA	FINLAND	FRANCE	GEORGIA	GERMANY
Population (million inhab.)	8.2	10.3	7.8	10.29	4.38	0.7	5.38	1.4	5.20	61.26	5	82.2
Number of interviews for consent	-	-	-	-	75	-	-	40	-	-	-	-
Number of family refusals	-	-	-	15	22	-	-	26	-	712	-	-

COUNTRIES	GREECE	HUNGARY	ICELAND	ISRAEL	ITALY	LATVIA	LUXEMB.	MALTA	T. NETHERL.	NORWAY	POLAND
Population (million inhab.)	11	10	289.272	6.7	56.30	2.3	0.4	0.4	16	4.52	38.23
Number of interviews for consent	89	233	-	130	1854	-	-	-	-	117	649
Number of family refusals	14	9	-	76	553	-	-	-	-	30	64

COUNTRIES	PORTUGAL	R. IREL.	ROMANIA	SLOVEAK R.	SLOVENIA	SPAIN	SWEDEN	SWITZERL.	U .K.	AUSTRALIA	USA	CANADA
Population (million inhab.)	10	3.8	21	5.3	2	42.72	8.9	7.2	59.0	19.88	291.5	31.63
Number of interviews for consent	-	-	10	73	36	1937	-	-	-	-	-	-
Number of family refusals	-	-	2	13	8	386	-	-	-	-	-	-

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International data on tissues and hematopoietic stem cell transplant activity Year 2003

TISSUE ACTIVITY INDICATORS 2003

COUNTRIES	CROATIA	FRANCE	GREECE	ISRAEL	ITALY	NETHERL.	POLAND	PORTUGAL	ROMANIA	SPAIN	SWEDEN	SWITZER.	U. K
Population (million inhab.)	4.38	61.26	11	6.7	56.30	16	38.23	10	21	42.72	8.9	7.2	59.0
Músculo-skeletal tissue													
Nº Cadaveric donors	20	-	6	15	187	96	582	-	2	523	-	-	-
(rate)	(4.57)		(0.5)		(3.3)	(6)	(15.32)		(0.1)	(12.24)			
Nº living donors	458	-	-	-	1739	1725	493	-	7	2925	-	-	-
(rate)	(104.57)				(30.9)	(107)	(12.97)		(0.33)	(68.46)			
Nº grafted patients	394	-	-	-	2499	1046	6834	-	14	5767	-	-	-
(rate)	(89.95)				(59.72)	(65)	(179.8)		(0.67)	(135)			
Nº bank processed pieces	5	10948	-	-	3444	6268	13104	-	-	9370	-	-	-
(rate)					(58.37)	(392)	(344.8)			(219.33)			
Percentage of desestimation	-	25.8	-	-	18.28	25	-	-	-	17.2	-	-	-
Types of tissues distributed:	-	-	-	-	-								
Bone						25/ 14/ 57	85/5.2/9.8	-	-	59.5/ 40/0.5	-	-	-
frozen/ freeze-dry/ demineralizated													
Types of tissues distributed:	-	3	-	-	-	4	-	-	-	2.2	-	-	-
Tendon													

TISSUE ACTIVITY INDICATORS 2003

COUNTRIES	CROATIA	FRANCE	GREECE	ISRAEL	ITALY	NETHERL.	POLAND	PORTUGAL	ROMANIA	SPAIN	SWEDEN	SWITZER.	U. K
Population (million inhab.)	4.38	61.26	11	6.7	56.30	16	38.23	10	21	42.72	8.9	7.2	59.0
Corneas													
Nº Cadaveric donors	4	-	76	253	6493	1682	571	355	2	1267	389	47	1764
(rate)	(0.91)		(6.9)		(115.3)	(105)	(15.03)	(35.5)	(0.1)	(35.02)	(43.7)	(6.5)	(29.9)
Nº grafted patients	-	-	211	-	4818	674	550	579	100	2626	602	-	2326
(rate)			(19.2)		(95.58)	(42)	(14.47)	(57.9)	(4.76)	(61.5)	(67.6)		(39.4)
Nº bank processed pieces	-	7425	-	-	11762	1140		-	-	1465	-	-	2301
(rate)					(229.04)	(71)	763			(36.52)			
Percentage of desestimation	31	45.9	-	-	51.7	60	(20.08)	-	-	13.6	-	-	-

TISSUE ACTIVITY INDICATORS 2003

COUNTRIES	CROATIA	FRANCE	GREECE	ISRAEL	ITALY	NETHERL.	POLAND	PORTUGAL	ROMANIA	SPAIN	SWEDEN	SWITZER.	U. K
Population (million inhab.)	4.38	61.26	11	6.7	56.30	16	38.23	10	21	42.72	8.9	7.2	59.0
Vascular tissue													
Nº Cadaveric donors	-	-	-	-	216	56	16	-	-	185	-	13	-
(rate)					(3.8)	(4)	(0.42)			(4.33)		(1.8)	
Nº grafted patients	-	-	-	-	184	-	-	-	-	74	-	-	-
(rate)					(3.3)				-	(1.73)			
Nº bank processed pieces	-	1754	-	-	192	3	16	-		272	-	-	-
(rate)					(5.04)	(0.2)	(0.42)			(6.36)			
Percentage of desestimation	-	53.6	-	-	771	17	20	-		23	-	-	-
Types of tissues distributed:	-	333	-	-	(11.29)	(1)	(0.53)		-				
Artery					42.76	60	-	-		95	-	-	-
Types of tissues distributed:	-	405	-	-	-	100	100	-	-	-	-	-	
Vein									-				-
Valves													
Nº Cadaveric donors	2	-	-	36	251	349	196	-	-	241	94	23	-
(rate)	(0.46)			(1)	(4.5)	(21)	(5.16)			(5.64)	(10.6)	(3.2)	
Nº living donors	-	-	-	-	7	14	-	-	-	3	23	-	-
(rate)					(0.1)	(0.9)				(0.07)	(2.6)		
Nº grafted patients	-	-	-	-	93	127	176	-	-	94	-	-	-
(rate)					(2.55)	(8)	(4.63)			(2.2)			
Nº bank processed pieces	-	596	-	-	476	352	270	-	-	388	-	-	-
(rate)					(8.54)	(22)	(7.11)			(9.08)			
Percentage of desestimation	-	74.5	-	-	50.5	60	-	-		32.7	-	-	-
Types of tissues distributed:	-												
Aortic/ Pulmonary		113/110	-	-	-	22/ 78	65/ 35	-		46/46	-	-	-
Types of tissues distributed:	-												
Tricuspid/ Mitral		0/ 27	-	-	-	-	10	-		0/ 8	-	-	-

TISSUE ACTIVITY INDICATORS 2003

COUNTRIES	CROATIA	FRANCE	GREECE	ISRAEL	ITALY	NETHERL.	POLAND	PORTUGAL	ROMANIA	SPAIN	SWEDEN	SWITZER.	U. K.
Population (million inhab.)	4.38	61.26	11	6.7	56.30	16	38.23	10	21	42.72	8.9	7.2	59.0
Skin													
Nº Cadaveric donors	-	-	17	-	208	341	16	-	3	76	7	-	-
(rate)					(3.7)	(21)	(0.42)		(0.14)	(1.73)	(0.79)		
Nº living donors	768	-	-	-	12	-	33	-	5	2	-	-	-
(rate)	(175.349)				(0.2)		(0.87)		(0.24)	(0.04)			
Nº grafted patients	738	-	-	-	1318	-	182	-	19	45	-	-	-
(rate)	(168.49)				(23.41)		(4.79)		(0.9)	(1.05)			
Nº bank processed pieces	-	209000	-	-	287926	190815	-	-	-	196949	-	-	-
(rate)					(5113.6)	(11925)				(4610.2)			
Percentage of desestimation	-	24.1	-	-	17.1	-	-	-	-	17.2	-	-	-
Cell Cultures													
Nº Cadaveric donors	-	-	-	-	-	-	-	-	-	-	-	-	-
(rate)													
Nº living donors	-	-	-	-	-	-	-	-	-	-	-	-	-
(rate)													
Nº grafted patients	8	-	-	-	-	-	-	-	-	101	-	-	-
(rate)	(1.83)									(2.36)			
Nº bank processed pieces	-	-	-	-	-	-	-	-	-	100	-	-	-
(rate)										(2.34)			
Percentage of desestimation	-	-	-	-	-	-	-	-	-	-	-	-	-
Types of tissues distributed:	-	-											
Chondrocytes			-	-	-	-	-	-	-	57.4	-	-	-
Types of tissues distributed: Keretinocytes	-	-	-	-	-	-	-	-	-	20.7	-	-	-
Types of tissues distributed:	-	-	-	-	-	-	-	-	-	-	-	-	-
Other										0.2			

HEMATOPOIETIC STEM CELL TRANSPLANTS 2003

COUNTRIES	CROATIA	FRANCE	GREECE	POLAND	PORTUGAL	SLOVEAK R.	SLOVENIA	SPAIN
Population (million inhab.)	4.38	61.26	11	38.23	10	5.3	2	42.72
Autologous	78	3072	103	498	164	118	32	1371
Allogeneic related	28	665	87	191	97	27	7	434
Allogeneic unrelated	4	305	14	107	13	0	4	130
Total	110	4042	204	796	274	145	43	1935

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RECOMMENDATION REC(2003)12 OF THE COMMITTEE OF MINISTERS TO MEMBER STATES ON ORGAN DONOR REGISTERS

Adopted by the Committee of Ministers on 19 June 2003 at the 844th meeting of the Ministers' Deputies

The Committee of Ministers, under the terms of Article 15.b of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve greater unity between its members and that this aim may be pursued, inter alia, by the adoption of common regulations in the health field;

Having regard to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (the Convention on Human Rights and Biomedicine) (ETS No.164);

Having regard to the Additional Protocol to the Convention on Human Rights and Biomedicine concerning the Transplantation of Organs and Tissues of Human Origin (ETS No. 186);

Bearing in mind that:

- the Protocol concerning the Transplantation of Organ and Tissues of Human Origin requires member states to have a legally recognised system specifying the conditions under which removal of organs or tissues is authorised;

- by virtue of Article 8 of the said protocol, member states should take appropriate measures to inform the public, namely about matters relating to consent or authorisation with regard to the removal of organs or tissues from deceased persons;

- Article 17 of the said protocol prohibits the removal of any organ or tissue unless the consent or authorisation required by national law has been obtained by the person proposing to remove the organ or tissue;

Recalling the general principles relating to data protection of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108),

Recommends to governments of member states to conform with the principles contained in the appendix to this recommendation as regards organ donor registries:

APPENDIX TO RECOMMENDATION REC(2003)12

1. Careful consideration should be given to the need for, and purpose of, an organdonor register.

2. In those member states with a legal framework for organ donation which assumes people are willing to donate their organs or tissues unless they have registered their refusal (opt-out system), states must provide an effective means for people to register their decision. A national register can be an effective means of recording such decisions.

3. For member states in which consent to donation is actively sought from the donor and/or those close to them prior to organ donation (opt-in system), an organ donor register may also fulfil important functions:

- as a means of registering the wishes of people willing to donate their organs;

- as a means of improving the efficiency of the organ and tissue donation process by making those wishes available rapidly after the death of a potential donor has been confirmed;

- as a means of publicising organ donation, and of involving people and organisations in realising the benefits of organ donations for themselves and for others in society;

4. Consideration should be given to the primary function of the organ donor register. Organ donor registers may:

- be opt-out only;

- be opt-in only;

- register both choices, or even a third choice, such as "ask my relatives";

- allow simply a general agreement to donate organs and/or tissues;

- allow wishes about the donation of particular organs and/or tissues to be specified;

- allow registration of wishes with respect to other sensitive procedures, such as post-mortem examinations or the donation of organs/tissue for medical research.

5. Organ donor registers should ensure, that:
- people wishing to register their wishes can do so easily and reliably;
- people can, if they wish, specify organs and tissues they do/do not wish to donate;
- people can revoke their entry at any time;
- all information on people who die is removed from the organ donor registry.

6. If the organ donor register is intended to facilitate organ donation it must:
- have details of a high proportion of potential donors/non-donors. If enquiries about potential donors give no results, health professionals will consider it a waste of time trying to access the register;
- enable easy and rapid twenty-four hour access by health professionals needing information about a potential donor.

7. Careful consideration should be given to the costs and benefits of setting up and maintaining an organ donor register:
- member states operating an opt-out system should, as a minimum, have a central register for those who do not wish to donate organs or tissues or any particular organ or tissue;
- a centrally-run information technology-based organ donor register offers the greatest flexibility in terms of content, updating and rapidity of access, but data security has to be ensured;
- everyone should be able to register their wishes;
- registration must be easy, preferably by both written and/or electronic means;
- written confirmation should be sent to all who register;
- people should have a simple means of checking and amending their entry
- specified healthcare professionals such as intensive care staff and/or transplant co-ordinators must have twenty-four-hours-a-day access to check the wishes of potential donors by phone, fax or electronically. Such checks should normally be made only after the death of a potential donor;
- checking the register could be made mandatory as a condition of donation.

8. Member states with organ donor registers should consider whether their register is designed and operated in a way which best meets the needs of their population and transplant service. Those member states which have an organ donor register are advised to consider the purposes and the likely advantages and disadvantages before establishing a new organ donor register.

RECOMMENDATION REC(2003)10 OF THE COMMITTEE OF MINISTERS TO MEMBER STATES ON XENOTRANSPLANTATION AND EXPLANATORY MEMORANDUM

Adopted by the Committee of Ministers on 19 June 2003
at the 844th meeting of the Ministers' Deputies

PREAMBLE

The Committee of Ministers, under the terms of Article 15.b of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve a greater unity between its members;

Having regard to the European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine and its Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin;

Having regard to the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes;

Having regard to the Resolution of the Committee of Ministers (78) 29 on the harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances, the Final Text of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987) and the Recommendation R (97) 15 of the Committee of Ministers to member states on xenotransplantation;

Bearing in mind Recommendation 1399 (1999) of the Parliamentary Assembly on xenotransplantation;

Bearing in mind recent reports from the OECD, the WHO and other national and international organisations;

Taking into account the shortage of organs and tissues of human origin available for transplantation;

Considering that xenotransplantation might be one of the possible therapeutic responses to this shortage;

Noting that xenotransplantation remains largely an experimental activity and that research is essential for the achievement of progress in this field;

Aware of the risks of rejection and illness xenotransplantation may cause in the recipient patient;

Mindful of the considerable risks which might arise from xenotransplantation in the field of public health and the transmission of diseases;

Considering that it is the responsibility of each member state to adopt adequate measures in order to address them and conscious that in some countries no appropriate regulations exist;

Considering that public health concerns require common provisions applicable in all the member states of the Council of Europe in which xenotransplantation is envisaged;

Considering that worldwide cooperation between states in this field is necessary;

Considering that no clinical xenotransplantation research should take place unless sufficient efficacy and safety is demonstrated through pre-clinical research;

Conscious that the need for such a demonstration will considerably limit the number of xenotransplantations in the coming years, thus allowing for an appropriate risk assessment;

Considering that xenotransplantation of cells and tissues is already being carried out in a number of states and that stringent regulations are thus urgently required;

Mindful of the social, ethical, cultural, legal and psychological problems which might be associated with xenotransplantation;

Mindful of the ethical and welfare issues associated with the use of animals for xenotransplantation and the associated research;

Noting the public concern over the issues related to xenotransplantation and stressing the importance of undertaking a public debate on this subject,

A. Recommends that the governments of member states:

- take the necessary measures to put their legislation and practice in the field of xenotransplantation in conformity with the following principles and guidelines with a view to minimising the risk of transmission of known or unknown diseases and infections to populations;
- co-operate in the setting-up of world-wide surveillance procedures and agreements;
- ensure a wide dissemination of this recommendation, in particular among all persons, organisations and

bodies, public or private, responsible for organising and carrying out xenotransplantation;

- take steps to make the provisions of this recommendation subject to public debate.

B. Decides that this recommendation will be re-examined at appropriate intervals and not later than in three years' time.

C. Instructs the Secretary General to bring the contents of this recommendation to the attention of the non-member states and international organisations which have participated in its preparation and to invite them to participate in the setting-up of an international surveillance network.

GUIDELINES

Chapter I - Object, scope and definitions

Article 1 - Object of the recommendation

This recommendation aims

- to protect, in both the short and long term, public health, patients, their close personal contacts and the professional staff involved in xenotransplantation, and

- to provide adequate protection for the animals used in xenotransplantation.

Article 2 - Scope of the recommendation

This recommendation covers all xenotransplantation activities involving human beings as recipients.

Article 3 - Definition

For the purpose of this recommendation, xenotransplantation is defined as any procedure that involves the transplantation or infusion into a human recipient of:

- live animal cells, tissues or organs, or

- human body fluids, cells, tissues or organs that have had ex vivo contact with live animal cells, tissues or organs.

Chapter II - General provisions

Article 4 - Xenotransplantation - the setting

No xenotransplantation should be carried out in a member state that does not provide regulation for xenotransplantation activities in conformity with the provisions of this recommendation.

Article 5 - Xenotransplantation authorisation

No xenotransplantation activity should be carried out in a member state unless authorisation is given by a body officially recognised as competent for this purpose, in accordance with the provisions contained in the following two paragraphs:

1. Authorisation for clinical xenotransplantation research should only be given if:

a. pre-clinical research has demonstrated, in accordance with internationally accepted scientific standards, that:

i. in the light of current scientific knowledge it is highly probable that there is no risk, in particular of infection, for public health;

ii. the potential level of efficacy and safety for the patient may justify the intervention having regard to the risks incurred;

b. all substantive and procedural conditions generally applicable to clinical research are fulfilled.

2. Xenotransplantation should not be authorised other than in clinical research unless, on the basis of clinical data:

i. there is adequate evidence, in accordance with internationally accepted scientific standards, that no risks, in particular of infection, to the general population exist, and

ii. the therapeutic benefit of the xenotransplantation has been established.

Article 6 - Xenotransplantation teams and centres

No xenotransplantation should be carried out unless it is undertaken by an accredited team in an authorised centre.

a. The teams carrying out the xenotransplantation should be appropriately qualified and comprise all the necessary scientific and medical expertise.

b. The centres should have received an authorisation by the competent bodies prior to beginning the xenotransplantation.

Chapter III - Protection of Public Health

Article 7 - Public Health protection plan

Member states should have a plan in place to address any events, in particular of infection, possibly related to a xenotransplantation which could compromise public health.

In particular, public authorities should take appropriate measures, in conformity with the principles of necessity and proportionality, to respond to events of transmissible or previously unknown illness related to xenotransplantation. These measures, if exceptional circumstances so require, might include isolation.

Article 8 - Collection and storage of biological samples and information

Information and biological samples concerning the source animals used in xenotransplantation and the recipients should be collected and stored in order to ensure traceability and long-term monitoring.

Article 9 - Follow-up

1. All protocols for clinical research should be accompanied by a plan to ensure the traceability and monitoring of the recipients, their close personal contacts and the professional staff involved in xenotransplantation in order to detect and deal with any adverse events, in particular of infection, possibly related to xenotransplantation.

The plan should include communication without delay to the competent body at national level of any such events.

2. Any xenotransplantation other than in clinical research should be accompanied by a plan to:

- ensure the traceability of the recipient as well as, depending on the circumstances, of other persons mentioned in paragraph 1;

- monitor, wherever necessary, the persons mentioned in paragraph 1.

The plan should include communication without delay to national public health authorities of any events, in particular of infection, possibly related to xenotransplanta-

tion and which could be of relevance to public health.

Article 10 - Precautions relating to the transmission of disease

All appropriate measures, in accordance with internationally recognised criteria, should be taken to prevent the risk of transmission of infectious agents from source animals.

Only animals bred specifically for xenotransplantation should be used. An appropriate Quality Assurance system encompassing all the stages from the production of the source animals to the final collection of the xenotransplants should be set up.

Article 11 - Prohibition relating to the use of non-human primates

1. Non-human primates should not be used as source animals for xenotransplantation.

2. Exceptionally, authorisation for the xenotransplantation of cell lines obtained from non-human primates may be given if:

- the conditions under Article 5 are fulfilled, and
- specific protective measures for these animals have been addressed. This implies that Great Apes should not be used as source animals in xenotransplantation.

Chapter IV - Protection of patients and close personal contacts

Article 12 - Conditions for patient participation

No xenotransplantation should be carried out unless the following specific conditions are fulfilled:

i. There is no other appropriate therapeutic method of comparable effectiveness available for the patient.

ii. The data resulting from pre-clinical research suggest or, where appropriate, the data resulting from prior clinical research indicate a clear therapeutic benefit for the xenotransplantation patient. In particular these data should:

- have demonstrated an adequate function of the xenotransplant in relevant models for an appropriate period of time through a clinically applicable methodology,
- provide sufficient reasons to believe that rejection can be overcome and that the xenotransplant can function adequately in humans.

iii. The risks which may be incurred by the patient are not disproportionate to the potential therapeutic benefit of the procedure.

In particular, the evaluation through pre-clinical research of the risks for adverse events and transmission of infectious agents to the recipient, as based on international standards for laboratory results and diagnostic assays, should have demonstrated sufficient safety.

Article 13 - Information to be given to patients

1. Patients participating in a xenotransplantation should be adequately informed in a comprehensible manner of the nature, objectives, possible benefits, potential risks and consequences of the procedure, as well as of any constraints that may be linked to it.

2. In particular patients should also be made aware of the constraints of monitoring and precautionary measures that may become necessary subsequent to xenotransplantation. Such measures will, according to the principles of necessity and proportionality, be adapted to the circumstances and adjusted in accordance with the assessment, based on current scientific and medical knowledge, of the risks generated by each of the procedures involved, and may in particular include:

a. the collection of personal data and inclusion in a register;

b. the provision by the medical team, in accordance with Article 14, of information concerning the risks of infection and the constraints associated thereto;

c. long-term medical monitoring including repeated biological samples being taken and archived;

d. reporting any significant unexplained symptoms or illness that may arise after the xenotransplantation;

e. maintaining contact with the medical team;

f. taking precautions with respect to sexual activity;

g. the need for the patient to agree that information is provided by a medical team to any future close personal contacts, in accordance with Article 14, concerning the risks of infection and the constraints associated thereto;

h. the other constraints which might be applicable if circumstances so require, in particular the possibility of isolation which may become necessary in the event of a contagious or previously unknown illness occurring.

3. Patients should be informed that, in accordance with Article 21, constraints mentioned hereinabove may be imposed if the person concerned refuses to comply with them.

Article 14 - Information to be given to close personal contacts of the patient

To protect close personal contacts and warn of the possible risks they might pose to the general public, the patient's close personal contacts should, with his or her consent, be informed by the medical team of the patient's envisaged participation in a xenotransplantation, of the risks of infection and of the consequences for them of such participation, and in particular, of the constraints which may be applicable.

The patient should also ensure that such information is provided to any future close personal contacts.

Article 15 - Information to be given to the professional staff involved in xenotransplantation

Professional staff involved in xenotransplantation should be fully aware of the risks of infection as well as the possible consequences and constraints which may derive from their participation in xenotransplantation.

Article 16 - Consent to xenotransplantation

1. No xenotransplantation should be carried out without:

i. the documented, specific, free and informed consent of the patient to the procedure and any necessary specific constraints; and

ii. the provision by the patient to the medical team of the necessary information concerning his or her current close personal contacts and the acceptance by the patient that his or her current and future close personal contacts be given information in accordance with Article 14.

2. Prior to xenotransplantation, the consent to carry out the intervention may be freely withdrawn at any time.

Article 17 - Counselling and support

The patients and their close personal contacts should be given proper information and have access to counselling and support by experts outside the team both before and after the xenotransplantation. This informing and counselling process should include the biomedical, ethical, psychological and social aspects of xenotransplantation.

Article 18 - Right to medical care

A refusal to participate, or a withdrawal of consent prior to the xenotransplantation, should not prejudice the patient's right to receive all other appropriate medical care in due course. The patient's consent to participate in a xenotransplantation should not prejudice his or her right to benefit from an allotransplant that becomes available while awaiting xenotransplantation, if medically indicated.

Article 19 - Patients not able to consent

1. Where xenotransplantation has been authorised for use other than in clinical research according to Article 5 paragraph 2, it may be carried out on a person not able to consent only if the following conditions are fulfilled:

- there is no therapeutic alternative of comparable effectiveness available to the patient,
- taking into account the constraints and conditions to which the person will or may be subjected according to Articles 13 and 14, the intervention is expected to result in a direct and important benefit for the patient, and
- the representative or an authority or a person or body provided for by law, after receiving the information referred to in Article 13, has authorised both the intervention and the provision of the necessary information to the present and future close personal contacts of the patient.

2. Patients unable to consent should not undergo clinical xenotransplantation research as referred to in Article 5, paragraph 1.

Exceptionally, a patient unable to consent may participate in a clinical xenotransplantation research intervention if the following specific conditions are fulfilled:

- there is adequate indication, on the basis of prior clinical research, that the xenotransplantation might be lifesaving,
- there is no alternative means of saving the life of the patient,
- taking into account the constraints and conditions to which the person will or may be subjected according to Articles 13 and 14, the intervention is expected to result in a direct and important benefit for the patient, and
- the representative or an authority or a person or body provided for by law, after receiving the information referred to in Article 13, has authorised both the patient's participation in the clinical xenotransplantation research and the provision of the necessary information to the present and future close personal contacts of the patient.

Article 20 - Confidentiality

All personal data relating to the recipient person and, where such data exist, their close personal contacts should be considered to be confidential.

Without prejudice to the provision of Article 8, such data should be collected, processed and communicated according to the rules relating to professional confidentiality and personal data protection.

Article 21 - Compulsory constraints

If, after the xenotransplantation has been carried out, the recipient or his or her close personal contacts refuse to comply with the constraints associated with xenotransplantation, public authorities should intervene and take appropriate measures, where public health protection so requires, in conformity with principles of necessity and proportionality.

Depending on the circumstances and in accordance with the procedures provided for by national law, such measures might include registration, compulsory medical follow-up and sampling.

Chapter V - Protection of animals

Article 22 - Compliance with animal protection regulations

All animal use in xenotransplantation should comply with the provisions of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes including the principles of Appendix A and Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of member states regarding the protection of animals used for experimental and other scientific purposes including Annex II.

These provisions should apply to source animals in addition to their sires and dams in source production units, pre-transplantation holding facilities, tissue harvest areas and during transport.

Article 23 - Husbandry, care, use and requirements of animals

The husbandry and care for all animals used in xenotransplantation should take account of their physiological, social and behavioural needs and should be designed to ensure their well being, particularly where breeding animals are maintained for long periods. The pain, suffering or distress and the number of animals used should be minimised.

Article 24 - Responsibility for husbandry and care of animals

There should be clearly assigned and documented responsibilities for husbandry and care of the animals used in xenotransplantation from birth to death, with a sufficient number of appropriately trained and competent staff available to inspect and care for them.

Article 25 - Surgical derivation and early weaning techniques

Surgical derivation and segregated/medicated early weaning production techniques should only be used where essential to produce animals of appropriate health status for use in xenotransplantation.

Article 26 - Transport of animals

Transport of animals for xenotransplantation should be kept to a minimum. If transportation is necessary, adequate arrangements should be made for the dispatch, receipt, acclimatisation and quarantine of animals in order to minimise the associated stress. The relevant

national and international legislation/regulations (including European Union Directive 95/29/EEC modifying Directive 91/628/EEC on the protection of animals during transport, and the European Convention for the Protection of Animals During International Transport (revised)) should be complied with.

Article 27 - Organ and tissue procurement from animals

Analgesia or anaesthesia should be used for the procurement of organs, tissues and cells for xenotransplantation, where it is necessary to minimise pain, suffering and distress of the animals.

If, as a result of the procurement, the subsequent health and welfare of the animals would be compromised, the animals should be killed by an appropriate method.

Sequential harvest of solid organs from individual animals should not be permitted.

Article 28 - Collection of animal records

Detailed records should be maintained of the derivation, source, use and final disposal of all animals bred for or used in xenotransplantation. Any unusual or unexpected traits or events should be recorded.

Article 29 - Pre-clinical research

The provisions of Articles 22 to 28 should also apply to animals used in pre-clinical research carried out to support clinical xenotransplantation research.

Chapter VI - Provisions relating to the ethical, social and psychological acceptability of xenotransplantation

Article 30 - Public debate

In accordance with the principles stated in Article 28 of the Convention on Human Rights and Biomedicine, member states should take active steps to ensure that the fundamental questions raised by xenotransplantation are the subject of appropriate public discussion particularly in light of relevant medical, psychological, cultural, ethical, legal, social and economic implications.

Chapter VII - Co-operation between parties

Article 31- International co-operation in medical research

Member states should co-operate through international surveillance procedures and agreements. They should also take appropriate steps to facilitate the co-ordination of research in xenotransplantation in order to improve its efficacy and safety, to avoid unnecessary duplication and to minimise animal use and suffering.

Article 32 - International co-operation in public health

Every member state should communicate without delay to national public health authorities of other member states and other concerned states any events, in particular of infection, possibly related to a xenotransplantation which could compromise public health.

Chapter VIII - Compensation for undue damage

Article 33 - Compensation for undue damage

The person who has suffered undue damage resulting from a xenotransplantation is entitled to fair compensation according to the conditions and procedures prescribed by law.

Chapter IX - Reports on the implementation of the recommendation

Article 34 - Implementation of the recommendation

On receipt of a request from the Secretary General of the Council of Europe any member state should furnish an explanation on the manner in which its legislation and practice in the field of xenotransplantation integrate the principles and guidelines of this recommendation, on any xenotransplantation activity and on any adverse event as referred to in Article 9.

RECOMMENDATION 1611 (2003)[1]

TRAFFICKING IN ORGANS IN EUROPE

1. Rapid progress in medical science and technology has transformed organ transplantation, and kidney transplantation in particular, into a routine medical procedure practised in hospitals across the world. Five-year survival rates for most organ transplantation programmes are reaching the level of 70%, thereby rapidly increasing the demand for organ donation.

2. Medical research demonstrates that renal transplantation increases the life expectancy of patients. The supply of organs from cadaveric, but particularly from living, donors is very limited and strictly controlled in Europe. There are currently 120.000 patients on chronic dialysis treatment and nearly 40.000 patients waiting for a kidney transplant in western Europe alone. Some 15% to 30% of patients die on waiting lists, as a result of chronic shortage of organs. The waiting time for transplantation, currently about three years, will reach almost ten years by the year 2010.

3. International criminal organisations have identified this lucrative opportunity caused by the "gap" between organ supply and demand, putting more pressure on people in extreme poverty to resort to selling their organs.

4. Worldwide, the issue of organ trafficking is not new. In the 1980s experts began to notice what was to become known as "transplant tourism" when prosperous asians began travelling to India and other parts of Southeast Asia to receive organs from poor donors. Since then other routes have opened up, such as to Brazil and the Philippines. Allegations have been made against China of commercial use of organs from executed prisoners. Organ sale continues in India despite new laws, which make the practice illegal in most regions.

5. While current estimations show that organ trafficking remains on a relatively modest scale in Europe, the issue is nevertheless of serious concern, since it is very likely that further progress in medical science will continue to increase the gap between the supply of, and demand for, organs.

6. As a result of poverty, young people in some parts of eastern Europe have sold one of their kidneys for sums of US$2 500 to US$3 000, while recipients are said to pay between US$100 000 and US$200 000 per transplant. It is a matter of grave concern that following illegal transplants the donor's state of health generally worsens in the medium term, due to the absence of any kind of medical follow-up, hard physical work and an unhealthy lifestyle connected to inadequate nutrition and a high consumption of alcohol. Most illegal donors will thus be forced in time to live on dialysis treatment or await, in turn, a kidney transplant.

7. This situation raises a number of ethical questions: Should the poor provide for the health of the rich? Should the price of alleviating poverty be human health? Should poverty compromise human dignity and health? And in terms of medical ethics, should help to recipients be counterbalanced by neglect of, and harm to, donors?

8. The Parliamentary Assembly therefore disapproves of recent trends in some western European countries towards less restrictive laws, which would allow greater scope for unrelated living donation.

9. Trafficking in organs –like trafficking in human beings or drug– is demand driven. Combating this type of crime should not remain the sole responsibility of countries in eastern Europe. Examples of measures to be taken by all member states in order to minimise the risk of organ trafficking in Europe include reducing demand, promoting organ donation more effectively, maintaining strict legislation in regard to living unrelated donors, guaranteeing the transparency of national registers and waiting lists, establishing the legal responsibility of the medical profession for tracking irregularities and sharing information.

10. The Assembly therefore recalls Committee of Ministers' Recommendation No. R (97) 16 on liver transplantation from living related donors, and Recommendation

1. Assembly debate on 25 June 2003 (21st Sitting) (see Doc. 9822, report of the Social, Health and Family Affairs Committee, rapporteur: Mrs Vermot-Mangold; and Doc. 9845, opinion of the Committee on Legal Affairs and Human Rights, rapporteur: Mr Dees).

Text adopted by the Assembly on 25 June 2003 (21st Sitting).

Rec(2001)5 on the management of organ transplant waiting lists and waiting times, and welcomes Recommendation Rec(2003)12 on organ donor registers.

11. The principle according to which the human body and its parts shall not, as such, give rise to financial gain is part of the legal acquis of the Council of Europe. This principle, already present in Resolution (78) 29 of the Committee of Ministers and confirmed, in particular, by the final declaration of the 3rd Conference of European Health Ministers, which was held in Paris in 1987, was enacted by Article 21 of the Convention on Human Rights and Biomedicine (ETS No. 164). The principle was reiterated in its Additional Protocol on Transplantation of Organs and Tissues of Human Origin (ETS No. 186), opened for signature in January 2002.

12. While the prohibition of organ trafficking is legally established in the Council of Europe member states, most countries still have legislative loopholes in this domain. Criminal responsibility in organ trafficking is rarely clearly specified in national criminal codes. Criminal responsibility should include brokers, intermediaries, hospital/nursing staff and medical laboratory technicians involved in the illegal transplant procedure. Medical staff who encourage and provide information on "transplant tourism" should also be liable to prosecution. The medical staff involved in follow-up care of patients who have purchased organs should be accountable if they fail to alert the health authorities of the situation.

13. Organ trafficking, like most criminal activities, is difficult to prove. But it should not be left to the media alone to investigate. Member states have a common responsibility to deal openly with this problem nationally, but also –through multilateral co-operation at European level– bringing together ministries of health, the interior and justice.

14. In the light of the above, the Assembly recommends that the Committee of Ministers:

i. invite all member states:

a. to sign and ratify the Convention on Human Rights and Biomedicine, and its Additional Protocol on Transplantation of Organs and Tissues of Human Origin;

b. to sign and ratify the United Nations Convention against Transnational Organised Crime and its Protocol to Prevent, Suppress and Punish the Trafficking of Persons, especially Women and Children, and the Optional Protocol to the Convention on the Rights of the Child on the Sale of Children, Child Prostitution and Child Pornography, as trafficking in organs is closely linked to trafficking in people;

c. to recognise their common responsibility in minimising the risk of organ trafficking by strengthening existing mechanisms of co-operation at the Council of Europe level by the Committee on the Organisation Aspects of Co-operation in Organ Transplantation (SP-CTO) and stepping up funding for assistance activities in this area, which is crucial in helping to put efficient transplant systems in place;

d. to adopt and apply the recommendations in the World Medical Association's (WMA) Statement on Human Organ and Tissue Donation and Transplantation, adopted by the 52nd WMA General Assembly in Edinburgh, Scotland, in October 2000;

ii. urge the member states to intensify their co-operation under the auspices of Interpol and Europol in order to address the problem of trafficking in organs more effectively. Stepping up the funding of the two agencies in this domain is equally crucial since they are both running on extremely low budgetary and staff levels in this field;

iii. invite the so-called "donor countries":

a. to improve primary prevention through awareness-raising and peer education, particularly in rural areas, in partnership with NGOs, the media, and relevant international agencies;

b. to undertake measures to improve primary health care;

c. to take steps to identify illegal donors and provide for their medical follow-up;

d. to strengthen existing transplant systems, with the assistance of the Council of Europe;

e. with legal support from the competent services of the Council of Europe, toamend, where necessary, their criminal codes, in order to ensure that those responsible for organ trafficking are adequately punished, including sanctions for medical staff involved in transplanting organs obtained through illegal trafficking;

f. to restrict the donation of organs and tissues from prisoners and other individuals in custody, as they are not in a position to give informed consent freely and can be subject to coercion, with the exception of donations for members of their immediate family;

g. to undertake effective measures to combat trafficking in general;

h. to provide special facilities at border crossings with a view to identifying potential victims;

i. to implement national anti-corruption programmes;

j. to implement national poverty reduction strategies and create conditions for investment;

iv. invite the so-called "demand countries":

a. to maintain strict laws in regard to transplantation from unrelated living donors;

b. to deny national medical insurance reimbursements for illegal transplants abroad;

c. to deny national insurance payments for follow-up care of illicit transplants, except where such a refusal would endanger the life or health of patients unable to cover the cost of vital treatment themselves;

d. to improve donor awareness by organising national campaigns and by actively supporting the regular organisation of the European Day for Organ Donation and Transplantation;

e. to take appropriate measures to encourage individuals to indicate, by means of statements of "consent", their wish to donate their organs after their death, in order to increase the availability of organs and tissues obtained post mortem;

f. to ensure strict control and transparency of organ

registers and waiting lists, and establish clear responsibilities for tracking irregularities;

g. to harmonise data and strengthen co-operation mechanisms for the allocation of organs in donation procedures;

h. to take steps to track down "broker" advertising (through newspapers, agencies, etc.);

i. to co-operate and provide expertise to "donor" countries in connection with trafficking in human beings and organs;

j. to ensure the flow of case-related information and provide necessary support to Interpol and Europol in this domain;

v. instruct the relevant bodies of the Council of Europe:

a. to develop, in co-operation with relevant organisations, a European strategy for combating trafficking in organs and to consider, in the framework of the drafting of the future convention on trafficking in human beings, the inclusion of an additional protocol covering trafficking in organs and tissues of human origin;

b. to advise and assist member states on organisational measures necessary for putting in place an efficient transplant system to minimise the risk of organ trafficking;

c. to provide legal assistance in drafting specific amendments to national criminal codes;

d. wherever applicable, to widen their existing activities to include organ trafficking;

vi. use its influence, in terms of more specific regional co-operation in South-eastern Europe, to broaden the activities of the Stability Pact Task Force on Trafficking in Human Beings (Working Table III) to cover the issue of trafficking in organs;

vii. call on all member states to demonstrate European solidarity towards the countries in eastern Europe which are most affected by the vicious cycle of poverty and to assist them, in co-operation with the international financing institutions and the international donor community, in developing measures to reduce poverty and create a secure business environment for investment.

RECOMMENDATION REC(2004)7/19 MAY 2004 OF THE COMMITTEE OF MINISTERS TO MEMBER STATES ON ORGAN TRAFFICKING

Adopted by the Committee of Ministers on 19 May 2004
at the 884th meeting of the Ministers' Deputies

The Committee of Ministers, under the terms of Article 15.b of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve greater unity between its members and that this aim may be pursued, inter alia, by the adoption of common action in the field of health;

Taking into account Resolution (78) 29 on harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances and the final text of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987), and the World Health Organisation Resolution WHA 42.5 condemning the purchase and sale of organs of human origin;

Having regard to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (ETS No. 164) and in particular to Articles 19 and 20 thereof;

Bearing in mind the requirements of the Additional Protocol to the above convention on Transplantation of Organs and Tissues of Human Origin, and in particular that Article 22 requires the prohibition of organ and tissue trafficking; that Article 3 requires member states to have a transplant system in place which allocates organs, and where appropriate tissues, only to those on the official waiting list; that Article 26 requires member states to provide for appropriate sanctions to be applied in the event of any infringement of the provisions contained in the aforementioned protocol; that Article 21 requires that the human body and its parts shall not, as such, give rise to financial gain or comparable advantage,

Considering that:

The universal shortage of organs and tissues can lead patients to a desperate search for a transplant which may involve unacceptable practices from a legal or ethical point of view;

Organ shortage can also encourage illegal organisations to traffic human beings for the purpose of organ transplantation, or to traffic organs obtained as a result of inducement or coercion;

Organ trafficking may undermine public confidence in organ and tissue transplantation services, decreasing the public's disposition to legitimate organ donation, thereby exacerbating the shortage of organs and tissues for transplantation,

Recommends that the governments of member states conform with the requirements set out in the appendix to this recommendation.

APPENDIX TO RECOMMENDATION REC(2004)7

Article 1 – Object

Member states should protect the dignity and identity of all persons and guarantee without discrimination their fundamental rights and freedoms with regard to organ and tissue transplantation.

Member states should make it clear to all that organ trafficking exploits human beings and is illegal, and should take all possible measures to prevent organ trafficking (see Article 4).

Article 2 – Scope and definitions

1. The provisions of this recommendation shall apply to all living persons and to the removal of organs, tissues and cells from those recently deceased.

2. The provisions of this recommendation applicable to tissues shall apply also to cells, including haematopoietic stem cells.

3. The provisions of this recommendation do not apply to blood or blood derivatives.

4. For the purposes of this recommendation the term "organ and tissue trafficking" applies to:

• the transportation of a person to a place for the removal of organs or tissues without his or her valid consent;

• the transportation of a person to a place for the removal of organs or tissues with his or her consent but in contravention of legislation or other controls in operation in the relevant jurisdiction;

• the transplantation of removed organs and tissues, whether transported or not, in contravention of legislation or other regulations in operation in the relevant jurisdiction or in contravention of international legal instruments.

5. For the purposes of this recommendation:

• the term "transplantation" covers the complete process of removal of an organ or tissue from one person and implantation of that organ or tissue into another person, including all

procedures for preparation, preservation, storage and transportation;

• the term “removal” refers to removal from the body of an organ or tissue intended for transplantation, by a surgical procedure or by other means.

Article 3 – Prevention

Prevention of organ trafficking should be undertaken in an integrated way by:

• Improving organ and tissue availability by well-established means such as those described in the Council of Europe consensus document “Meeting the organ shortage: current status and strategies for improvement of organ donation” (1999);

• Approving a legal framework which strictly forbids any kind of commercialisation of the human body and its parts consistent with the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (ETS No. 164). Legislation should be extended to citizens going abroad. However, medical care should not be denied;

• Assuring the traceability of human organs and tissues through the accreditation and control of centres for procurement and/or transplantation, tissue banks, and the follow up of patients;

• In the case of a living donor transplant, member states should provide for official authorisation of all such transplants;

• In all cases where the living donor is a foreign citizen, the relevant officially recognised bodies in the country of transplantation and in the home country of the living donor must be informed;

• In the case of a living donor, all payments to the donor should be strictly prohibited and considered a criminal offence.

This provision should not apply to payments which do not constitute a financial gain or a comparable advantage, in particular:

- compensation of living donors for loss of earnings and any other justifiable expenses caused by the removal or by related medical examinations;
- payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation;
- compensation in case of unjustified harm resulting from the removal of organs or tissues from living donors.

Article 4 – Legal instruments

1. Member states should ensure that there are legal instruments in place which prohibit the trafficking of persons for the purpose of organ or tissue transplantation and the trafficking of organs and tissues themselves.

2. Member states should ensure that those legal instruments prohibit:

• the removal of organs and tissues except in centres or circumstances recognised for the purpose and by health professionals with appropriate training and experience;

• the implantation of organs and tissues except in centres or circumstances recognised for the purpose and by health professionals with appropriate training and experience;

• financial gain from the human body or parts of the body intended for transplantation;

• advertising with the intention of securing persons or organs or tissues for trafficking or for financial gain;

• organising or running an organisation or service involved in organ or tissue trafficking.

3. Member states shall ensure that legislation provides for appropriate sanctions to be applied in the event of any infringement of the provisions of this recommendation.

Article 5 – The transplantation system

1. Member states shall ensure the provision of a nationally recognised transplantation system which guarantees equitable access to transplant services.

2. National transplant waiting lists should be established in compliance with the Committee of Ministers' Recommendation Rec(2001)5 on the management of organ transplant waiting lists and waiting times.

3. The system shall ensure that:

• appropriate information is recorded on all organs and tissues removed for the purposes of transplantation;

• all organs, and where appropriate tissues, are only allocated to persons who are on a nationally recognised waiting list;

• appropriate information is recorded on all organs and tissues used for implantation or other purposes;

• information on the risks associated with organs obtained illegally is provided.

4. The information provided should ensure traceability from donor to recipient but shall be collected, processed and communicated in accordance with regulations relating to confidentiality and personal data protection.

Article 6 – International co-operation

1. Organ trafficking is a universal problem. Therefore international co-operation is required to combat it.

2. Member states should ensure full co-operation with all other states and with international agencies, including law enforcement agencies, in order to combat organ trafficking, and apply the sanctions provided for in this recommendation to any person or entity involved in organ trafficking.

3. Member states should present a full report of any allegations or instances of organ trafficking within their territory to the Secretary General of the Council of Europe.

Article 7 – Information for the general public

Member states should ensure that the general public is fully informed about organ trafficking and the penalties which may be incurred. In particular:

• accurate information about organ and tissue donation and transplantation should be provided;

• organ and tissue donation should be promoted as positive behaviour that contributes to saving lives and improving the health of many people;

• false reports on organ trafficking may alarm the general public and adversely affect organ and tissue donation and should be refuted.

RECOMMENDATION REC(2004)8/19 MAY 2004 OF THE COMMITTEE OF MINISTERS TO MEMBER STATES ON AUTOLOGOUS CORD BLOOD BANKS

Adopted by the Committee of Ministers on 19 May 2004
at the 884th meeting of the Ministers' Deputies

The Committee of Ministers, under the terms of Article 15.b of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve greater unity between its members and that this aim may be pursued, inter alia, by the adoption of common action in the field of health;

Taking into account Resolution (78) 29 on harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances and the final text of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987);

Having regard to the European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (ETS No. 164) and in particular to Articles 19 and 20 thereof;

Having regard to the Additional Protocol to the Convention on Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine concerning the Transplantation of Organs and Tissues of Human Origin (ETS No. 186);

Considering that:

The principal current use of blood cells collected at the time of birth from the umbilical cord (cord blood) is the collection of haematopoietic progenitor cells (HPC) that can be transplanted into patients with acquired or congenital diseases of the bone marrow. It is likely that such cells will, in the future, constitute a valuable source of cell therapies for the treatment of a wide range of diseases;

Cord blood stored only for autologous use, that is, by the donor or his or her immediate family, is only very rarely used. Furthermore, there is no scientific evidence that umbilical cord blood can be stored for long enough to be of any use to the vast majority of donors. Such storage could limit altruistic donation and thereby limit the possibility of treating those in need;

The unregulated collection of blood at the time of birth could distract the staff caring for mother and child at a critical time;

Even if it is the case that these children do, in the future, develop diseases requiring an HPC transplant, there is evidence to suggest that it is preferable to use allogeneic transplantation to achieve the “graft vs. tumor effect” in hematological diseases. In cases of congenital disease and in some leukaemias with intrauterine cell mutations, autologous HPC transplantation is contraindicated;

The health services of member states should only provide their citizens with proven clinical and cost effective therapies as resources are always limited;

With the aim of ensuring the availability of transplant treatments for an increasing number of people,

RECOMMENDS TO THE MEMBER STATES THAT,

1. If cord blood banks are established, they should be based on altruistic and voluntary cord blood donation and used for allogeneic transplantation and related research;

2. The promotion of donation for autologous use and the establishment of cord blood banks for autologous use should not be supported by member states or their health services;

3. Accurate information should be provided to the population about the advantages and disadvantages of cord blood banks;

4. Where autologous cord blood banks are being established, the promotional material or information provided to families must be accurate, and fully informed consent to cord blood storage must be obtained;

5. Autologous cord blood banks that are being established must meet the quality and safety standards set out in the Council of Europe's Guide to safety and quality assurance for organs, tissues and cells.

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HELLENIC NATIONAL
TRANSPLANT ORGANIZATION

6th European Day of Organ Donation and Transplantation

Athens, 2004 September 18th